Screening Definition Document

SCENARIOS TO BE IMPLEMENTED FOR SEARCHING POTENTIAL SUBSTANCES OF CONCERN FOR SUBSTANCE EVALUATION AND REGULATORY RISK MANAGEMENT
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1. Introduction

The screening for (potential) substances of concern is relevant for several REACH\(^1\) and CLP\(^2\) processes:

- Community Rolling Action Plan (CoRAP) under **Substance Evaluation (SEv)**;
- Compliance check under **Dossier Evaluation (CCH)**;
- Potential further regulatory risk management measures under the REACH and CLP Regulations i.e.:
  - Harmonised Classification and Labelling (CLH);
  - Authorisation - Identification of Substances of Very High Concern (SVHC);
  - Restriction.

Since 2013, ECHA is applying a common screening approach, which covers the needs of most of the above mentioned processes. For details on the general screening approach for REACH and CLP processes, please refer to the document available on ECHA website\(^3\).

The definition document does not contain specific scenarios for compliance check. However as a result of manual screening, authorities can conclude that compliance check is needed before conclusions can be made on the need for the above processes if the suspected hazard cannot be confirmed due to a data gap in a directly related endpoint.

The purpose of the definition document is to define search criteria (so called screening scenarios) to identify/select substances of concern. The four chapters of the definition document have been developed in parallel defining:

- Non-hazard criteria and scenarios to support identification of CoRAP candidate substances (exposure related criteria) but also to aid the selection of more relevant substances before less relevant ones for possible further regulatory risk management actions (e.g. CLH, SVHC).
- Human health (HH) screening scenarios;
- Environment (ENV) screening scenarios (focusing for the time being on PBT properties);
- Endocrine Disruptor (ED) screening scenarios (covering both HH and ENV);

The scenarios in the four chapters are applied to all substances within the scope of the various processes and their outcome is stored in a master list that is annually refreshed and distributed to MSCAs. The master list is also the basis for ECHA to prepare lists of a pool of potential candidate substances to be manually screened by authorities (so called short lists). In chapter 7 criteria for the preparation of the short lists are also developed and reflect the screening priorities for this round of screening.

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3. The ‘Common Screening Approach for REACH and CLP Processes’ document can be found in the Screening Interest Group on CIRCABC. Example path: /CircaBC/echa/Screening.
The following are the indicative timelines associated with a Screening Round, which is carried out in collaboration between ECHA/COM and MSCAs.

The different parameters listed in the chapters are not considered to be a final set of parameters and scenarios. Refinement of the parameters and scenarios as well as the use of additional ones is foreseen in the future.

2. Purpose and pool of substances

2.1. Substance Evaluation

Substance Evaluation (SEv) aims at verifying whether a substance constitutes a risk for human health and/or the environment. SEv is performed by MSCAs on substances listed in the Community Rolling Action Plan (CoRAP).

In accordance with Article 44 of the REACH Regulation, ECHA applies risk-based prioritisation criteria for the selection of substances and prepare annual updates of the CoRAP, which have to be submitted to the Member States by 28 February each year. The selection of substances to be included in the CoRAP should be risk based, which means both hazard (intrinsic properties) and exposure aspects should be taken into account when selecting substances for SEv.

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The aim of the scenarios (mainly exposure related) described in this document is to identify CoRAP candidate substances, when applied to a pool of substances already found to meet the CoRAP screening scenarios developed in the HH, ENV and ED screening scenario chapters (i.e. with potential concern for carcinogenicity, mutagenicity, reproductive toxicity (CMRs), skin and/or respiratory sensitisation and/or in relation to ED or PBT/vPvB properties). Together, these two elements of hazard and exposure/risk criteria will enable a risk based approach in selection of substances for CoRAP.

Which candidate substances will finally be proposed to be included in the list of CoRAP candidates will depend on the outcome of the manual screening process to be performed following the IT assisted mass screening described in this document.

2.2. Risk Management

There is a need to be able to identify potential substances, for which further regulatory risk management under REACH or CLP Regulations may be needed. These substances could be:

- Candidates for Harmonised Classification and Labelling (CLH);
- Substances of Very High Concern (SVHCs) or
- Substances for which it is necessary to impose a restriction on a Community-wide basis.

2.2.1. Harmonised Classification and Labelling

Substances that fulfil the criteria set out in Annex I to the CLP Regulation for carcinogenicity, mutagenicity and/or reproductive toxicity (CMR) properties, category 1A, 1B or 2, and respiratory sensitisation (RS), category 1, 1A or 1B should normally be subject to harmonisation of classification and labelling.

When a substance fulfils the CLP criteria for hazard classes other than CMR and RS, harmonisation of classification and labelling may also apply, if justification is provided demonstrating the need for such action at Community level (CLP, Art. 36). One of the possible justifications would be the need for confirming the hazard class to support the SVHC identification and inclusion in the Candidate List.

In addition, for active substances in Plant Protection Products (PPP) and Biocidal Products (BP), harmonisation of classification and labelling applies for all hazard classes meeting the CLP criteria for which the MSCA submitting the CLH proposal provides the necessary information, assessment and conclusion.

The CLH screening scenarios described in the HH chapter will result in a large number of potential CLH candidates. As mentioned already in the introduction further criteria (non-hazard) will need to be applied to narrow the pool of substances and focus attention on the most critical ones. As CLH should be seen as the first step in identifying substances as SVHCs for those that do not already have a harmonised classification, it is proposed to use the same criteria as for SVHC substances.

Therefore, the aim of the scenarios described in this document is to identify good candidate substances for CLH, when applied to a pool of substances found to meet the CLH screening scenarios in the HH chapter. Together, these two elements of 1) hazard based search and 2) non-hazard criteria will enable to select first substances considered of “higher priority” for further work.
Which substances will finally be identified as CLH candidates will depend on the outcome of the manual screening process performed following the IT assisted mass screening.

2.2.2. SVHC identification (1st step in the authorisation process)

SVHCs are substances that meet the criteria laid down in Article 57 of REACH\(^5\). They are substances which:

- Meet the CLP criteria for classification in the hazard classes carcinogenicity, mutagenicity and/or reproductive toxicity (CMRs) category 1A or 1B;\(^6\)
- Meet the criteria as PBT or vPvB as laid down in Annex XIII of REACH;\(^6\)
- Could give rise to a level of concern for human health (HH) equivalent to CMRs, e.g. endocrine disruptors, respiratory sensitisers, STOT RE or (perhaps) skin sensitisers;\(^6\)
- Could give rise to an equivalent level of concern to PBT or vPvBs (e.g. endocrine disruptors).\(^6\)

The SVHC Roadmap to 2020\(^7\) gives priority to substances with SVHC properties which are registered for uses within the scope of authorisation. The aim is to carry out screening activities covering the following substance groups:

For HH:

- CMRs (cat 1A/1B);
- Sensitisers;
- Endocrine disruptors (EDs);
- Substances with Specific Target Organ Toxicity (STOT RE).

For ENV

- PBTs or vPvBs;
- Endocrine disruptors (EDs).

Furthermore, the SVHC Roadmap to 2020 gives priority to substances which have been registered for non-intermediate uses. Therefore screening (and Risk Management Option (RMO) analyses) of these registered substances are referred to as the “Core Activities” in the SVHC Roadmap implementation plan\(^8\).

In addition, various “Supplementary Activities” are planned for in the SVHC Roadmap implementation plan. Such activities are or will be carried out to identify:

- Further harmonised classified or self-classified (potential) SVHC substances, which are registered for uses as intermediate only, or substances which are not registered but

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\(^5\) Whether the SVHC criteria of REACH article 57 are met is formally being concluded on by the Member State Committee (MSC). If the MSC is unable to find unanimous agreement, the European Commission takes over for a formal conclusion.

\(^6\) ECHA is advocating that SVHC identification should only be initiated after a harmonised C&L entry has been included in Annex VI of CLP.


\(^8\) The draft ‘Roadmap Implementation Plan’ can be found at the following link on ECHA website: [http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan](http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan)
notified. Focus will be on those substances which are similar\(^9\) to the substances identified under the core activity;

- Further (potential) PBT/vPvB substances structurally similar to the PBTs with registrations for non-intermediate uses (and therefore may be taken forward together with these latter substances during RMO development) but with registration(s) as intermediate only or not being registered but notified.

The differentiation between core and supplementary activity is not intended to indicate priority but rather to recognise what is core to the SVHC Roadmap implementation and what supplementary work is needed (in parallel) to feed into that core activity.

The SVHC Roadmap to 2020 has introduced the need to define “selection criteria” (called “non-hazard criteria” in this document) to be applied to the pool of substances meeting the human health (HH), environment (ENV) or ED search criteria as the application of the hazard based search criteria may result in a large number of potential SVHC candidates. Application of these non-hazard criteria may need to take place (and is foreseen in the RIP\(^8\)) at the following stages:

- When deciding which substances on the mass screening outcome lists are of high relevance for further assessment of PBT/vPvB, ED, sensitising or CMR properties;
- When selecting substances for further clarification of their PBT/ED/CMR/sensitising/STOT RE properties (e.g. via Compliance Check or Substances Evaluation) in cases where there is not enough information available to conclude.

Examples of such criteria are high volume, uses in the scope of authorisation and wide dispersive use.

The aim of the scenarios described in this document is to identify potential SVHC substances which, in line with the SVHC Roadmap to 2020 objectives, need to be further screened first. These scenarios will be applied to a pool of substances already found to meet the SVHC search criteria developed in the HH, ED and ENV screening scenario chapters (i.e. with harmonised classification for carcinogenicity, mutagenicity, reproductive toxicity (CMRs), skin and/or respiratory sensitisation and/or with ED or PBT/vPvB properties).

Together, these two elements of search (hazard) and non-hazard criteria will enable to select for further work first substances that are more relevant than others.

All substances found to be of higher relevance (from hazard point of view) will be further prioritised based on non-hazard criteria. The aim is to use non-hazard criteria to prioritise the most relevant substances first, but ultimately all substances meeting the hazard criteria should be screened.

Which substances will finally be identified as SVHC candidates will depend on the outcome of the manual screening process performed following the IT assisted mass screening.

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\(^9\) As defined in the Roadmap Implementation Plan
2.2.3. Substances requiring restriction

Restriction under REACH may be necessary to limit a risk on a Community wide basis in cases where a substance poses an unacceptable risk from the manufacture or uses as such, in a mixture or in an article.

When it comes to screening for (potential) substances for restriction, the aim is to find substances to be further assessed to identify an unacceptable risk. Such substances could be SVHCs or non-SVHCs but their selection must be risk based. As a consequence hazard based scenarios (HH, ENV or ED) have to be combined to exposure/risk based scenarios in order to be able to identify potential restriction candidates.

So far restriction screening scenarios are not described in the different chapters of the definition document. Potential cases which warrant initiation of the restriction process are likely to be identified only in manual screening phase, or later in the process based on SEv and/or RMOA.

2.3. Starting pool of substances

The scenarios developed in this document include scenarios suitable for identifying substances that may be good candidates for harmonised classification and the supplementary activities of the SVHC Roadmap. These scenarios can apply to substances for which ECHA has not yet received a registration dossier, such as substances for which only notifications in the C&L inventory have been received up to now (e.g. for CMR). Other scenarios, and particularly those for Substance Evaluation, may apply only to substances for which ECHA has received a registration dossier. Hence, with the expansion of the portfolio of scenarios, it is necessary to have clear definitions for the different types of registrations and, consequently, types of substances in order to succinctly describe the technical implementation of the scenarios. The purpose of this section is to provide these definitions.

The starting pool of substances for all common screening activities comprises the approximately 120 000 substances in the C&L inventory\(^\text{10}\) and, additionally, substances that have been notified under the Dangerous Substances Directive, but for which ECHA has not yet received an updated registration dossier or C&L notification\(^\text{11}\).

The registrations and notifications that are screened fall under one of the categories described in Table 1.

\(^{10}\) Please note that all registrations are also included in the C&L inventory.

\(^{11}\) In principle manufacturers or importers of such notified substances should have submitted a registration dossier with the GHS classification, but the algorithm does not rely on this and explicitly includes notified substances in the starting pool.
Table 1: Categorisation of registrations/notifications

<table>
<thead>
<tr>
<th>Group</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH registrations</td>
<td>Registrations that are not associated with a prior notification under the Dangerous Substances Directive</td>
</tr>
<tr>
<td>Tonnage upgraded NONs registrations</td>
<td>For these registrations there is a notification but ECHA has received a REACH dossier that contains higher information requirements compared with the original notification due to a tonnage upgrade (detected using a conservative implementation with emphasis on the information requirements)</td>
</tr>
<tr>
<td>Updated NONs registrations</td>
<td>For these registrations there is a notification but ECHA has received a REACH dossier that has not increased the information requirements compared with what was needed under the Dangerous Substances Directive</td>
</tr>
<tr>
<td>Non-updated NONs registrations</td>
<td>For these registrations ECHA has not yet received a REACH dossier</td>
</tr>
<tr>
<td>Notifications in the C&amp;L inventory</td>
<td>These are notifications in the C&amp;L inventory submitted according to Article 39 of the CLP Regulation, that are not due to registrations (every registration is also a notification, but such registrations belong to one of the categories above)</td>
</tr>
</tbody>
</table>

3. Non-hazard screening criteria

3.1. Introduction

This chapter will explain the non-hazard criteria (indicators and scenarios) and their proposed implementation in the screening process.

Different set of non-hazard criteria may be used depending on the scenarios and activities covered as illustrated in Figure 1.

The non-hazard criteria used so far are:

- Exposure and use criteria;
- Structural similarity approach.

In addition it has been suggested in the SVHC Roadmap that further non-hazard criteria (e.g. time to obtain information) could be used to further refine for instance the list of potential CoRAP candidates. This could help deciding which substances should be notified on the CoRAP first in case many substances would still be available after applying the first set of criteria. These criteria are not further developed in this document.

The use of the non-hazard criteria is further developed below as well as illustrated in Figure 1.
3.1.1. Proposed criteria for CoRAP, CLH and SVHC Roadmap Core activities

The non-hazard criteria are mainly exposure and use related to support the risk based CoRAP selection and the selection of substances of higher priority for SVHC and CLH. The non-hazard indicators and scenarios will be used on the top of the hazard scenarios (further described in the chapters on HH, ENV and ED) when preparing the short lists of substances for manual screening. This is in order to have as high priority for further work those substances fulfilling the risk based scenarios of CoRAP, those for which exposure (e.g. high tonnage, wide dispersive use) and regulatory action (e.g. uses in the scope of authorisation) are expected.

It should be emphasized here that the criteria developed and proposed in this chapter aim not only at identifying substances with high potential for exposure to human health and/or releases to the environment but also to identify those substances for which there is evidence of no or low potential for exposure/release and relevance (e.g. no uses of relevance for authorisation or substance evaluation). This approach is intended to reduce the number of
false negatives (and bring in false positives which are then detected at the stage of the manual screening).

The main scenarios proposed to be used for short listing are scenarios to identify substances with wide dispersive or widespread uses in the scope of regulatory action.

Non-hazard scenarios are described further below as well as non-hazard indicators which have been used in the past and for which there is already a general agreement that they are useful in the context of screening.

In addition, indicators such as the tonnage of the substance will be extracted and could be further used for short listing.

After manual screening, different lists of substances will be available as highlighted in Figure 1.

### 3.1.2. Proposed criteria for SVHC Roadmap supplementary activities

As introduced in section 2.2.2, the aim of the supplementary activities of the SVHC Roadmap is to identify potential candidate substances for manual screening only registered as intermediates or not registered but for which a C&L notification has been received and which are similar to substances already identified and in the pool of substances for RMO.

In this chapter, a non-hazard similarity scenario to be used at the stage of short listing is described, i.e. the scenario that gives a hit for those substances that are similar to a substance for which regulatory actions are currently on-going or have been performed. That scenario corresponds to the box “short list non-hazard criteria: structural similarity approach” in Figure 1.

### 3.2. Tonnage - Aggregated tonnages

#### 3.2.1. Definition

Tonnage or aggregated tonnage is a necessary parameter needed for screening purposes. When we refer to aggregated\(^{12}\) (or total) tonnage we mean the sum of total tonnage per substance across all registration dossiers (full, Transported Isolated Intermediate (TII) and On Site Isolated Intermediate (OSII)) i.e. the sum of full pie chart in Figure 2 below.

From this ‘overall total tonnage’ we need the following further breakdown:

- Total manufacture and use tonnage from TII dossiers (REACH Article 18);
- Total manufacture and use tonnage from OSII dossiers (REACH Article 17);
- Total manufacture and use tonnage from “full” registration dossiers (REACH Article 10):
  - Non-intermediate tonnage;
  - Intermediate tonnage (not under strictly controlled conditions (SCC)).

The total use tonnage is defined as the total manufactured tonnage + total imported tonnage – tonnage directly exported.

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\(^{12}\) Here we interpret ‘aggregated tonnage’ and ‘total tonnage’ as being the same thing. In that case we interpret the word ‘aggregated’ meaning “whole formed by combining several separate elements” (dictionary.com)
### 3.2.2. Current limitations and proposed implementation

For the time being it is not possible with the current IUCLID fields to identify the full tonnage going into uses as intermediates (combining intermediates under strictly controlled conditions and intermediates under non-strictly controlled conditions).

The same applies for defining the tonnage going into transported isolated or on-site isolated intermediates reported in full registration dossiers, as even though the fields to report this information are available in IUCLID, these are not systematically filled in and therefore we may need to base the tonnage value on the tonnage band for the dossier rather than on a fixed value entered in a specific field. It has to be kept in mind that the tonnage band might not reflect the reality of the use of the substance but will nevertheless be used as a surrogate in case no other information is available.

It is therefore proposed to use the following information to generate the aggregated tonnage numbers relevant for screening. First as mentioned in section 3.2.1 total manufacture and use tonnages will be retrieved for the different dossiers.

In addition for each reported tonnage the following information is reported to give a better understanding of the manufacture and use trend depending on the years (e.g. increase in the tonnage, decrease in the tonnage, fluctuations over years):

- Maximum total use tonnage (full, TII and OSII) for the last year reported;
- Average total use tonnage (full, TII and OSII);

This information will be retrieved at the level of dossiers and later on aggregated at the level of the substance.

### 3.2.3. Future implementation in IUCLID 6.1

The final proposal is to have in IUCLID 6.1 the following information on tonnage:

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13 The figure is just shown as an example and does not represent any real example of a substance.
In section 3.2 – “Estimated quantities” the reporting of information on (aggregated) tonnage per year of the registered substance with minor changes compared to previous IUCLID version.

In section 3.5 (“Life cycle description”):
- A new section on use and exposure information relevant for all uses containing cumulative tonnage information such as:
  - Cumulative tonnage for use at industrial sites, for widespread uses by professional workers, for consumer uses, for service life;
  - Free text field to report details on, for instance, the source of information and how the tonnage was calculated and;
  - Check box to specify if the tonnage reported is equal to the EU tonnage.
- Tonnage of the substance per use with supporting information to correctly interpret the tonnage reported;
- Registration/notification status for the use allowing to identify if it is:
  - A use registered according to REACH Article 10 with a tonnage manufactured/imported ≥ 10 tonnes/year per registrant,
  - A use as intermediate registered according to REACH Article 10 with a tonnage manufactured/imported ≥ 10 tonnes/year per registrant,
  - A use registered according to REACH Article 10 with a tonnage manufactured/imported < 10 tonnes/year per registrant,
  - A use as intermediate registered according to REACH Article 10 with a tonnage manufactured/imported <10 tonnes/year per registrant,
  - A use registered according to REACH Article 17/18,
  - A use reported by downstream user according to REACH Article 38.
- Indication whether the use has a particular regulatory status (e.g. use as motor fuels, use in biocidal products) (see section 3.3.3).

3.3. Relevant uses for selection of substances

3.3.1. Definition

Substances only used in uses outside the scope of authorisation or substance evaluation or substances for which there are uses further exempted from these processes could get lower priority than other substances. Therefore, it would be useful to identify such uses to give substances with such uses a low priority for further work.

Below an overview of the uses exempted/outside the scope of substance evaluation or authorisation is presented.

Uses exempted/outside the scope of Substance Evaluation:
Uses exempted from Authorisation:

- Scientific Research and Development - Art. 56(3);
- Use in medicinal products (wscl) – Art. 2(5)(a);
- Use in food and feeding stuffs (wscl) – Art. 2(5)(b);
- Intermediates - Art. 2(8);
- Use in Plant Protection Products (wscl) - Art. 56(4)(a);
- Use in biocidal products (wscl) - Art. 56(4)(b);
- Use in motor fuels (wscl) - Art. 56(4)(c);
- Use in certain other fuels – Art. 56(4)(d);
- Use in medical devices (wscl) – Art. 60(2);
- Manufacturing process of a substance;
- Use of substances in imported articles.

Note that some exemptions listed in the legal text have a limited scope and only apply when the substance is identified as SVHC only because of hazards to human health (e.g. risks to human health from uses in cosmetic products (wscl) – Art. 56(5)(a) & 67(2) or risk to human health from uses in food contact materials (wscl) – Art. 56(5)(b)). The uses covered by these specific exemptions are not listed above and are not considered further in the scenarios due to the difficulty in determining whether the conditions of the exemption are met.

In addition it should be kept in mind that use of substances in imported articles cannot be subject to authorisation as regulatory measure.

3.3.2. Current limitations and proposed implementation

The current situation doesn’t allow unequivocal automated identification of the uses according to their regulatory status in a mass-processing context. A weight of evidence approach has to be applied, combining different sources of information and search approaches, which entails a certain level of uncertainty.

It is therefore proposed to use the following information currently retrievable from the IUCLID dossiers to support identification of the exempted uses (sole or in combination):

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14 within scope of Community legislation (wscl)
• Dossier template/header and tonnage band (differentiation between Art. 10 registration (full registration) and Art. 17 and 18 registration (registration of intermediates used under strictly controlled conditions));

• List of keywords present in the use names eventually combined with product categories (PCs) or technical function;

• Life-cycle stages eventually combined with information on tonnage.

We propose that we do not attempt to develop separate criteria for filtering out uses for SEv and SVHC. The reason is that the differences in scope are relatively narrow compared with the uncertainty due to the quality of the use and exposure information in the registration dossiers. Hence, uses are categorised into two big groups, those that are subject to regulatory actions and those that seem to be either exempted or of lower priority for both Substance Evaluation and Risk Management.

3.3.3. Future implementation in IUCLID 6.1

In IUCLID 6.1 it will be possible for each use to indicate the following:

• Registration/notification status for the use allowing to identify if it is:
  o a use registered according to REACH Article 10 with a tonnage manufactured/imported ≥ 10 tonnes/year per registrant;
  o an intermediate use registered according to REACH Article 10 with a tonnage manufactured/imported ≥ 10 tonnes/year per registrant;
  o a use registered according to REACH Article 10 with a tonnage manufactured/imported < 10 tonnes/year per registrant;
  o an intermediate use registered according to REACH Article 10 with a tonnage manufactured/imported <10 tonnes/year per registrant;
  o an intermediate use registered according to REACH article 17/18;
  o a use reported by downstream user according to REACH article 38.

• Regulatory status of the use:
  o Use in scientific research and development;
  o Use in Plant Protection Products;
  o Use in biocidal products;
  o Use as motor fuels;
  o Use as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems;
  o Use in cosmetics products;
  o Use in food contact materials;
  o Use of the substance in mixtures below the concentration limit specified in REACH Art. 56(6)
This should enable identification of such types of uses in order:

- To identify substances which would have only uses exempted or outside the scope of authorisation (restriction)/substance evaluation:
- To give a better picture of the use pattern of the substance when for one substance both exempted and not exempted uses are present (in particular if in addition information on the tonnage per use is provided).

### 3.4. Wide dispersive use.

Wide dispersive use is one of the exposure criteria that can be used to support the selection of substances as potential candidates in the context of mass screening for the CoRAP and for the SVHC Roadmap to 2020.

Wide dispersive uses can be defined as:

- For the environment: widespread use (at many sites, by many users) with potential for release;
- For human health: widespread use (at many sites, by many users) with potential for exposure.

Wide dispersive use is clearly mentioned in REACH Article 58 as a criterion to support the prioritisation of substances to be recommended for inclusion in Annex XIV. The prioritisation approach has been revised in 2014. In this revised version a simplified approach is proposed to take into account the low level of information available in the registration dossiers particularly related to wide dispersive uses. The approach proposed in this document is consistent with the new approach developed for the Annex XIV prioritisation\(^{15}\). However, to support the mass screening and more particularly the selection of substances based on wide dispersive use with which we want to start working, it is expected that more information will be needed to be able to discriminate among the high number of substances in the pool of substances screened, compared to the starting pool of substances in the context of Annex XIV prioritisation. Therefore we have developed an approach relying on more information and parameters than what is currently proposed in the context of the Annex XIV prioritisation.

In addition it could be foreseen in the future to also use this criterion to support other REACH processes where wide dispersive uses are mentioned such as the selection of testing proposals where for instance the legal text (Article 40 (1)) mentions that priority shall be given to substances with “uses resulting in widespread and diffuse exposure”.

There will be no specific scenario implemented for wide dispersive use but by combining scenarios on the potential for exposure/release and how widespread is a use it will be possible to identify those substances with potential wide dispersive uses or on the contrary those substances with clearly no uses that can be wide dispersive.

3.4.1. Widespread uses / Non-widespread uses

3.4.1.1. Definition

A substance is considered to have **widespread uses** if there is at least one professional use or one consumer use or one service life stage use reported for that substance. In other words professional and consumer uses are expected to be done at many sites and/or by many users and the same applies to service life.

A substance is considered to have **non-widespread uses** if there are only uses at industrial and formulation settings and for these uses there are only few sites and/or few users involved.

3.4.1.2. Current limitations

As previously defined, widespread use means a use at many sites or by many users. To get clear indicators of how widespread is a use is not straightforward. For instance there is now the possibility in IUCLID to give an indicative number of sites per use. However although this information might be known by registrants for their direct customers at the beginning of the supply chain, this information will be less and less available as you go further down the supply chain, even already at the level of industrial uses. Therefore the information reported in IUCLID (if present at all) is less reliable. The number of users is usually not known or might be very specific to some formulation, specific industrial use stage if available.

This is the reason why it is proposed to use surrogate information to get an idea on how widespread a use can be.

3.4.1.3. Proposed implementation – Widespread uses

For identifying “widespread uses” it is proposed to use:

- Information on use description in IUCLID section 3.5 - Life cycle stages\(^{16}\): uses by professional workers, consumer uses and service life stage are (potentially) widespread by definition;

- Information from the SPIN database on the range of use (RoU) index indicating the number of applications for the substance is > 10;

- Information from the Chemical Data Reporting (CDR) database indicating commercial or consumer use;

The IUCLID information listed above is always available in the registration dossiers and together with information from external database will enable the selection of substances with potential widespread uses.

3.4.1.4. Proposed implementation - Evidence of non-widespread uses.

For identifying “non-widespread uses” it is proposed to use:

- Information on use description in IUCLID section 3.5 – Life cycle stages for uses at industrial / formulation settings:

\(^{16}\) Including differentiation according to “main user groups”
3.4.1.5. Future implementation in IUCLID 6.1.

IUCLID 6.1 will include the following improvements:

- Indication whether the substance is used only in a very limited number of industrial sites (only for formulation and industrial uses). In case the registrant would know that one use is used only in a very limited number of industrial sites then he would be able to select this option and to justify it (free text field);

- Tonnage of the substance per use with supporting information to correctly interpret the tonnage reported.

These new information should support the identification of substances with non-widespread uses.

3.4.2. Potential for release to the environment

3.4.2.1. Definition

The potential for release to the environment is defined as the potential for a substance to be released in one of the environmental compartments following the use of that substance. A substance that is fully contained will by definition have no (or very low) potential for release.

The potential for release to the environment may be estimated on the basis of the following information:

- The uses contained by their technical nature such as functional fluids, fully contained during their whole life cycle (e.g. refrigerating liquids, some textile “dry” cleaning systems, hydraulic fluids) should be of less relevance;

- For other uses, the actual release factors applied in the assessment by the registrant (including OC/RMM) as well as the tonnage per use may contribute to the selection.

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17 The number of registrants within a joint registration reporting those uses can also be taken into consideration.
3.4.2.2. Current limitations

As explained in section 3.1 it is easier to identify substances for which the potential for release to the environment is expected to be low rather than to try to differentiate among the substances for which the potential for release to the environment is expected to be high.

In order to differentiate those substances with a potential for release to the environment the descriptor system (ERCs default release factors) could be used for expressing the release potential. However, ERC default releases factors do not represent necessarily the reality of the use and could lead to inconsistencies. For instance some ERCs clearly defined as closed system may have a release factor higher than wide dispersive ERCs (e.g. ERC9 release factor of 5%). In addition ERCs default factors can be far from the reality observed on site for the use concerned when proper risk management measures (RMMs) and operational conditions (OCs) are in place. For that reason we propose to use only the ERC description and the fact that for ERC7 and 9 it is considered that the substance is fully contained during the use assuming no to very low release to the environment.

Another possibility could be to use the actual release factors (including OC/RMMs) used in the assessment as those release factors combined with the tonnage information are expected to reflect the actual emission to the environment for each compartment. However this information is so far rarely reported and therefore cannot be used as a discriminating factor.

In conclusion, it is proposed to use for the time being only the information on “the level of containment of the uses” of a substance as even though a field to report the release factors is available in section 3.7 of IUCLID this information is so far rarely reported and it is not possible to use it in a systematic way in the screening.

This section will be further revised in round 4 based on the new structure of IUCLID 6.1.

3.4.2.3. Proposed implementation – Evidence of low release to the environment

It is proposed to use for indicating a low potential for release to the environment the following:

- The only ERCs that appear in section 3.5 of IUCLID are ERCs 7 and 9 OR;
- The use index reported in the SPIN database for all the uses for that substance are between 0-2 (no indication of direct exposure to one of the environmental compartment).

For substances that fulfil these criteria, there is evidence that the substance is only used in conditions of low release to the environment.

3.4.2.4. Proposed implementation - Potential for release to the environment

It is proposed to use for indicating a “significant” potential for release to the environment the following:

- The use index reported in the SPIN database for that substance is more than 2 (one or several use indicate a potential exposure).
In theory all substances for which there is not only ERCs 7 and 9 should be considered with a potential for release however the use of the SPIN database scenario could help starting to work on substances where at least from the Nordic registries there is indication of potential exposure to the different environmental compartments.

3.4.2.5. Future implementation in IUCLID 6.1

IUCLID 6.1 will include the following improvements regarding description of conditions of use, potential for releases and exposures (exposure scenarios) for substances registered at more than 10t\(^1)\:

- Indication whether the use takes place under rigorously contained conditions or not:
  - a. At the level of each Exposure Scenario;
    - i. Checkbox: rigorously contained system with minimisation of releases to the environment.
  - b. At the level of each Contributing Activity for workers and environment;
    - i. Text area: Technologies to minimise emissions (only if check box "rigorously contained system with minimisation of releases to the environment" is selected).
    - ii. Particular considerations on the waste treatment operations, open list among which the following:
      - Treatment under rigorous containment conditions required.

3.4.3. Potential for exposure to humans

3.4.3.1. Definition

The potential for exposure to humans is defined as the potential for a substance to lead to exposure of humans (workers, consumers) following the use of that substance. A substance that is fully contained will, by definition, have no\(^2) (or very low) potential for exposure.

The potential for exposure to humans may be estimated on the basis of the following information:

- Level of containment: highly contained uses from an occupational exposure perspective should be of lower relevance;
- For non-contained processes, additional information on use pattern, such as PROCs and certain use conditions indicating high potential for exposure can be used, such as: aerosol forming processes or abrasive techniques; high scale of use, where even low dustiness materials can generate large quantities of airborne dust during transfers; use of dusty products, process at elevated temperature leading to a potential increase of the vapour pressure or even the formation of fumes, use of products containing the

\(^{18}\) For substances registered at less than 10t specific fields only relevant to REACH will also be available focusing on insignificant release/exposure.

\(^{19}\) Please note that no exposure is usually very difficult to achieve.
substance in high concentration, evidence on proximity of workers to the source of emission;

- Generally, high volatility or very dusty substances are most relevant to the potential for inhalation exposure and low volatility substances are most relevant to dermal exposure potential. There is usually a clear relationship between dustiness and inhalation but this may not exist quite as clearly for dermal exposure;

**3.4.3.2. Current limitations**

Like for the environment it is proposed, firstly, to identify substances with a use pattern indicating a low potential of exposure to humans rather than to try to identify those substances with a high potential of exposure. It is therefore proposed to first use information on the level of containment to deprioritise those substances with uses only highly contained use. For the time being if we were to only base our “lower prioritisation” on this criterion, there would still be many substances left over. This is because such a ‘high level of containment’ criterion is only based on a few PROCs indicating a closed system (PROCs 1 to 3) whereas other processes may also take place in closed systems (e.g. industrial spraying described by PROC7, treatment of articles by dipping and pouring described by PROC13).

For non-contained uses applying information on the use pattern and some key conditions of uses (information used as such or in combination) is envisaged. The relevant information would need to be available in a structured field in all registration dossiers. Part of this approach can already be implemented, as described in section 3.4.3.4, but it should be improved later with the update of IUCLID 6.1.

**3.4.3.3. Proposed implementation – Evidence of low potential for exposure to humans**

It is proposed to use for indicating a low potential for exposure to humans the following:

- No other PROCs reported than PROCs 1, 2, 3, 15, 16 and 20 in all dossiers for that substance/

It is considered that for substances indicating only those PROCs there is evidence that the potential to humans is low, and therefore are of less priority.

**3.4.3.4. Proposed implementation – Potential for exposure to humans**

It is proposed to use for indicating a significant potential for exposure to humans the following:

- At least one of the uses of the substance in the registration dossiers is reported with one of the following PROCs that cannot happen in closed system based on their definition (PROCs 5, 6, 11, 17, 19, 23).

We would propose not to use the vapour pressure as an indicator for the time being and to further develop it when looking at risk-based scenarios in future rounds of screening.
3.4.3.5. Future implementation in IUCLID 6.1

The current proposal for IUCLID 6.1 includes the following improvements regarding description of conditions of use, potential for releases and exposures (exposure scenarios):

- Indication whether the use takes place under rigorously contained conditions or not:
  a. At the level of each Exposure Scenario;
     i. Checkbox: rigorously contained system with strict control for manual interventions.
     ii. Text area: Description of non-technical means for strict control
  b. At the level of each Contributing Activity for workers;
     i. Text area: description of non-technical means for strict control (only if check box “rigorously contained system with strict control for manual interventions” is selected).
     ii. Text area: Rigorously contained system with strict control for manual intervention (only if check box “rigorously contained system with strict control for manual interventions”).

3.5. Technical function

It is proposed to retrieve for all substances the technical function associated to each use in order to facilitate later on the work on similarity of uses expected to be done at the level of the RMO. This information is therefore not as such a non-hazard criterion but is proposed to be retrieved systematically to facilitate the work at the level of RMO.

This information will be systematically retrieve for all substances selected for manual screening in a predefined format as well as information on uses and other potential relevant information on the substance. The retrieved information will be made available to the Member State in charge of the manual screening of the substance.

3.6. Exposure information in support of risk scenario

To support risk based scenarios for selecting potential candidates for the CoRAP or for restriction further exposure information may be needed. This is not described further in this document and will be developed later.

3.7. Similarity

The similarity regardless of the hazard is used as a prioritisation criterion for all supplementary activities of the SVHC Roadmap. No specific scenario is implemented but it is possible to identify substances that are similar to substances in the RMO pool.

The following broad topics have been considered when developing algorithms to find similarities among substances:
- Tanimoto-like structural distances based on chemical structures, i.e. two substances are considered similar if their structural distance calculated via the structural fingerprints is below a threshold
- structural alerts based on chemical structures, i.e. two structures are considered similar if they activate the same set of structural alerts (these can be generic chemistry ones if we do not focus on a particular endpoint or endpoint specific, such as OECD DNA binding alerts if we focus on mutagenicity)

As a mechanism of finding similar substances we also use read-across/categories submitted in the registration dossiers or introduced by other regulatory authorities, such as the OECD categories. This will be further explained in the definition document.

When it comes to supplementary activities under the SVHC Roadmap only structural similarity is considered.

### 4. Human health screening scenarios

This section of the document explains how the new HH screening scenarios to be implemented have been developed.

#### 4.1. CoRAP: Screening scenario logic.

The CoRAP screening scenarios focus on the identification of:

- Suspected carcinogens, mutagens, reproductive toxicants (developmental toxicity and/or fertility), in particular C, M or R/RD/RF/Rd/Rf individually or as combination C and M (CM) or CM category 2 or R for categories 1 or 2 without CM categories 1;

- Suspected sensitisers (skin or respiratory sensitisers).

From a purely hazard point of view, the scenarios rely on the classifications in Annex VI of the CLP Regulation (including Adaptations to Technical Progress - ATPs)\(^{20}\) and/or (self-) classifications in the registration dossier and/or on positive results reported for the endpoints in the registration dossiers. However, there are other criteria (such as exposure related criteria described in Section 3), which need to be applied to determine relevancy from a CoRAP point of view.

In some cases the information available in the registration dossier can possibly lead to [or: be sufficient to justify] a proposal for harmonised classification or a revision of an existing harmonised classification. In case there are obvious data gaps in the registration dossier(s) the substances may be selected for compliance check. If further data beyond the REACH Annexes needs to be required to evaluate a specific concern, those substances are relevant candidates for the CoRAP.

In this round, new scenarios are added for the endpoints carcinogenicity/mutagenicity and/or reproductive toxicity, for example:

- Scenarios based on computational modelling: these scenarios are intended to be used as additional alerts to support other scenarios, but not as stand-alone scenarios.

- Scenarios based on indicators for probably ambiguous results or indicators for adverse effects which the registrant did not consider warranting classification.

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\(^{20}\) Harmonised classification can only be checked in Annex VI of CLP (C&L Inventory Database) due to the fact that the IUCLID Section 2.1. can also include self classifications.
Scenarios based on external databases: these scenarios are intended to be used as additional alerts to support other scenarios, but not as stand-alone scenarios. External databases may contain additional information which is currently not provided by the Registrants and which may raise concern. This information can potentially provide support in the evaluation of other scenarios. Examples of such lists, are the IARC monographies, NTP Report on carcinogens (RoC) and the ISSTOX chemical toxicity databases (http://www.iss.it/ampp/?lang=1&id=233&tipo=7).

4.2. CLH: Screening scenario logic.

The **CLH screening scenarios** described in this document focus on substances with potential CMR, STOT RE or sensitising properties. The scenarios will not be limited to non-harmonised substances but will include cases where notifiers/registrants have indicated a more stringent classification than currently harmonised; for instance when a substance harmonised as carcinogen category 2 has been notified as carcinogen category 1B.

The scenarios for CLH can broadly be split into three categories:

- One aims at looking into self-classifications as reported in the REACH registration dossiers and in notifications to the C&L Inventory. For instance, a substance registered as Carc. Cat 1B or notified as such by a significant number of notifiers could be considered of potential concern and shortlisted for manual verification.
- Another category is identifying substances that are structurally similar to substances already harmonised for a specific classification and included on Annex VI.
- The third category of scenarios aims at analysing external sources such as assessments made by other regulatory bodies and identifying substances classified or recommended for classification in the hazard classes of concern. Examples of such lists are the IARC monographies, NTP Report on carcinogens (RoC) and the Inventory Multi-tiered Assessment and Prioritisation (IMAP) run by the National Industrial Chemicals notification and Assessment Scheme (NICNAS) of the Australian government.

The substances identified by the CLH scenarios are likely to be many. Some combination of the hazard scenarios will narrow the pool further but for a reasonable number of substances to be added to the short list for manual screening, further prioritisation based on non-hazard criteria is needed. These non-hazard criteria are further described in Section3. CLH is also a necessary first step in the process of SVHC identification for human health hazards. The CLH scenarios developed here will therefore also be used to identify candidates for supplementary activities under the SVHC 2020 Roadmap.

4.3. SVHC: Screening scenario logic.

The **SVHC screening scenarios** described in this section focus on substances with harmonised classification as CMR 1A/1B, Skin or Respiratory Sensitisers 1/1A/1B and/or STOT RE 1/2 at the level of the substance or its constituents (incl. impurities or additives). From a purely hazard point of view, the scenarios rely on the classifications in Annex VI of the CLP.
Regulation (including ATPs)\textsuperscript{21}. However, there are other non-hazard criteria (described in Section 3), which need to be applied to determine relevancy from an SVHC Roadmap point of view.

The SVHC Roadmap Implementation Plan divides activities into “Core activities” and the “Supplementary activities” (see Figure 3). The core activity referred to in the SVHC Roadmap Implementation Plan consists of substances for which the following is true:

- At least one currently active\textsuperscript{22}, full registration dossier (Article 10) has been submitted for the substance.

Note: this will be combined with the non-hazard scenario which is met if the full registration dossier contains at least one non-intermediate use\textsuperscript{23}.

The supplementary activities referred to in the SVHC Roadmap Implementation Plan, consists of substances for which the following is true:

- **(Supplementary Activity A)**
  - Registered and has a harmonised classification as CMR (1A or 1B), sensitisation and/or STOT RE
  
  AND

  - At least one currently active registration dossier has been received, which is:
    
    - A pure intermediate dossier (as on-site isolated intermediate or as transported isolated intermediate in accordance with REACH Articles 17 or 18) OR
    
    - Is a full registration in accordance with REACH Art. 10 (Note: this will be combined with the non-hazard scenario which is met if the full registration dossier contains only intermediate use\textsuperscript{23}
    
    AND

    - This will be combined with the similarity scenario which is met if the registration is for a substance which is structurally similar to the substances in the CMR/Sensitiser pool of substances on the Candidate list, in the registry of intentions for SVHC identification or under RMOA.

- **(Supplementary Activity B)**
  - Not registered, but notified to the C&L Inventory and has a harmonised classification as CMR (1A or 1B), sensitisation and/or STOT RE
  
  AND

\textsuperscript{21} For substances with harmonised CMR classification in Annex VI, it is important to compare the list of these known CMRs with the registration database and not to rely on the classification in section 2.1 of the IUCLID dossiers.

\textsuperscript{22} “Active” means not annulled, revoked, or reversibly ceased manufacture and/or import

\textsuperscript{23} A description on how uses are automatically categorised as intermediate and non-intermediate use will be provided in the ‘non-hazard criteria’ definition document, focussing on potential for exposure.
This will be combined with the similarity scenario which is met if the registration is for a substance which is structurally similar to the substances on the Candidate list, in the registry of intentions for SVHC identification or under RMOA.

- **(Supplementary Activity C)**
  - No harmonised classification for CMR (1A or 1B), sensitisation or STOT RE **AND**
  - At least one notification indicating CMR, sensitisation and/or STOT RE self-classification in the C&L inventory **AND**
  - At least one currently active registration dossier in accordance with REACH Articles 10, 17 or 18 has been received **AND**
  - This will be combined with the similarity scenario which is met if the registration is for a substance which is structurally similar to the substances on the Candidate list, in the registry of intentions for SVHC identification or under RMOA.

- **(Supplementary Activity D)**
  - Not registered **AND**
  - No harmonised classification for CMR (1A or 1B), sensitisation or STOT RE **AND**
  - At least one notification indicating CMR, sensitisation and/or STOT RE self-classification in the C&L inventory **AND**
  - This will be combined with the similarity scenario which is met if the registration is for a substance which is structurally similar to the substances on the Candidate list, in the registry of intentions for SVHC identification or under RMOA.

*Note on supplementary activities C and D:*
The screening needs for certain supplementary activities described under the SVHC Roadmap are more relevant for certain CLH and CoRAP screening scenarios, rather than SVHC scenarios. Therefore, when it comes to these activities, the substances identified using the CLH and CoRAP screening scenarios described in these document, can also be considered to cover the supplementary activities under the SVHC Roadmap.
Figure 3: Key steps in screening and identifying CMR/sensitiser/STOT substances (SVHC Roadmap to 2020 Implementation Plan (RIP)).

5. Screening scenarios for environment

5.1. Screening scenarios logic: Substance Evaluation and SVHC.

This section of the document explains the background of the proposed implementation of the PBT screening scenarios.

The aim of the CoRAP screening scenarios is to identify suspected PBT or vPvB substances whereas for SVHC scenarios the attention should rather be on PBT or vPvB substances for which no further data is needed. In reality at the level of the definition of the screening scenarios it is difficult to distinguish between suspected PBT/vPvB and PBT/vPvB as in any case an assessment of the data is needed before being able to conclude on the need for further information. As a consequence only very few scenarios will be specific to one process. Those scenarios are SVHC scenarios and are further described below.

The scenarios described below aim at identifying potential P, B and/or T substances at the level of substance, constituents, impurities and additives. Annex XIII of REACH (section 1) was used as a starting point for the cut-off values for identification of PBT/vPvB substances. Following first two screening rounds, we modified these cut-off values in order to increase the number of candidate substances and reduce the number of false negatives. This will be clearly
documented with the outcome of the mass screening. Those cut-off values will most probably continue to evolve over the years in order to find more candidates.

For constituents the same approach and scenarios as the one proposed at the level of the substance will be applied as developed further in the document. The starting point for the screening based on constituents will therefore be the registration data, when available, or experimental data available in external sources or the same prediction tools as used for substances. The use of external sources of information or of predictions will be possible only if information on the structure of the relevant constituents (impurities and additives) is available in the registration dossiers (IUCLID section 1.2) of the substance concerned. The use of predictions is not foreseen for all endpoints. At this point scenarios relying on predictions have been implemented for persistence (BIOWIN models used to predict biodegradability) and terrestrial bioaccumulation (KOAWIN and HENRYWIN models used to predict octanol/air partitioning coefficient and Henry’s Law Constant respectively).

Note that to facilitate the work of Member States it is also foreseen to cluster the potential PBT substances on the mass screening outcome list in order to avoid that similar substances are assessed by different Member States and if this is the case at least that Member States could cooperate while assessing the substances. Due to technical limitations it is not possible to have this clustering at the level of the Master List but this will be done at the level of short lists.

Under the SVHC Roadmap there are in addition supplementary activities (see Figure 4) which cover:

- The identification of substances likely to be PBT/vPvB which have been registered for intermediate uses only and are structurally similar to the registered substances already included in the PBT/vPvB pool under the core activity or to known PBT/vPvB substances (e.g. in the Candidate List).
- The identification of potential PBT/vPvB substances in the C&L inventory which are not registered but are structurally similar to substances already included in the PBT/vPvB or ED pool under the core activity or to known PBT/vPvB or ED substances (e.g. in Candidate List).

24 Known PBT/vPvB substances are those in the Candidate List or in the RMO pool.
5.1.1. Scenarios for Persistence

Scenarios for identifying substances that have potential P properties ("P scenarios") rely on: (1) the statement provided by the registrants (registrant declares that the substance is P or vP); (2) experimental data (ready biodegradation studies in the registration dossiers); and (3) BIOWIN model predictions.

Experimental data

Different P-scenarios have been developed for separating the substances based on reported reliability of the study taken into consideration.

Two types of scenarios search for suitable candidates based on ready biodegradation data in the registration dossiers:

1) Firstly, the biodegradation study summaries are taken into account. The substance fulfils the scenario if the registrant concludes in the endpoint summary for section 5.2.1 that no biodegradation is observed or the substance is not inherently biodegradable, or if for at least one water/sediment simulation endpoint summary or soil simulation endpoint summary the half-life meets the criteria of REACH Annex XIII.

2) Secondly, the ready biodegradation studies in the registration dossiers are checked to determine the highest percentage biodegradation across all reported endpoint studies. If
this value fails to pass the threshold set at 60%, the substance is selected. One scenario is applied only to reliable studies. Another scenario considers all studies, irrespective of reliability.

**BIOWIN predictions**

One set of scenarios uses BIOWIN model predictions in accordance with the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT Assessment, 2014, to identify substances with potential P/vP properties.

### 5.1.2. Scenarios for Bioaccumulation

Scenarios for identifying substances that have potential B properties ("B-scenarios") rely on: (1) the statement provided by the registrant (registrant has identified the substance as B or vB); (2) studies in the registration dossiers; and (3) additional information (model predictions and external databases).

Different B-scenarios have been developed for separating substances based on reported reliability of the study taken into consideration.

The following parameters are being used to assess potential B properties of the substance:

- Octanol/water partition coefficient ($K_{OW}$);
- Octanol/air partition coefficient ($K_{OA}$);
- Bioconcentration, bioaccumulation, biota-sediment accumulation, biomagnification factors and trophic magnification factors (BCF, BAF, BSAF, BMF, TMF).

**Octanol/water partition coefficient ($K_{OW}$)**

The ECHA Guidance for PBT assessment recognizes $K_{OW}$ as a parameter relevant for screening of substances with potential B properties. In Round 2 we assumed that for organic substances with a log $K_{OW}$ value below 4.0 the affinity for the lipids of an organism is insufficient to exceed the B criterion, i.e. a BCF value of 2000. Due to the fact that a decreasing relationship between the bioconcentration factor and the octanol/water partition coefficient is observed at very high log $K_{OW}$, an upper cut-off value of log $K_{OW} < 7.0$ was proposed. The values 4.0 and 7 were estimated based on the BCF max curve in Figure R.11-6 of the ECHA Guidance on information requirements and chemical safety assessment Chapter R.11: PBT and vPvB Assessment. However, following the Round 2 and the consultations with MSCAs, it has been agreed to modify the lower threshold to 3.0 in order to minimize the number of false negatives.

In Round3 B-scenarios identify the substances within the range log $K_{OW} = [3.0 - 7.0]$ as likely to meet the B criterion in REACH Annex XIII. Separate B scenarios have been developed to also identify substances with log $K_{OW} \geq 3.0$ but without an upper limit. These scenarios may identify substances with higher log $K_{OW}$ which may break down to bioaccumulative degradation products.

**Octanol/air partition coefficient ($K_{OA}$)**
The octanol/air partition coefficient (KOA) has been recognized as a parameter indicating that bioaccumulation can occur in air-breathing (terrestrial) organisms. Since reporting KOA is not required of the registrant under REACH, KOA had to be calculated based on the information available in the registration dossiers: KOW and Henry’s Law Constant (H). In case H was also unavailable, it was estimated based on water solubility (WS), vapour pressure (VP), and molecular weight (MW). For all cases where this information was not available, H was estimated using HENRYWIN model. In order to support the scenarios identifying substances (partially) relying on experimental data, scenarios using KOAWIN model directly estimating KOA were utilized. This group of B-scenarios will identify the substance as potentially bioaccumulative if the following applies: estimated log KOA ≥ 5 AND at least one log KOW ≥ 2. The cut-off values for KOA and KOW were established based on references from the scientific literature. Available studies indicate that chemicals with log KOA ≥ 5 have the inherent capacity to biomagnify in terrestrial food webs, while the chemicals with log KOW < 2 are being quickly eliminated by the urinary excretion, and therefore do not biomagnify even though their KOA is high.

Bioconcentration, bioaccumulation, biota-sediment accumulation, biomagnification and trophic magnification factors (BCF, BAF, BSAF, BMF, TMF)

B-scenarios relying on bioconcentration, bioaccumulation and biota-sediment accumulation factors (BCF, BAF, BSAF) are identifying substances based on values reported in the registration dossiers. The first cut-off value (BCF ≥2000) was taken from REACH Annex XIII and ECHA Guidance for PBT assessment. The second cut-off value (BCF, BAF or BSAF>1000) was implemented since this is an indication of bioaccumulation potential. Such results (>1000) reported in a registration dossier may not have been reported or interpreted correctly (for example if a fish BCF result was not lipid-normalised), and may in fact exceed the B criterion in REACH Annex XIII.

B-scenarios relying on a biomagnification factor (BMF) and trophic magnification factor (TMF) have been implemented separately, without reference to a cut-off value. The substance was selected if a BMF or TMF value was available in an endpoint study record.

5.1.3. Scenarios for Toxicity

Scenarios for identifying substances that have potential T properties ("T-scenarios") rely on: (1) the statement provided by the registrant (registrant has identified the substance as T); (2) studies in the registration dossiers indicating that substance fulfils the T criterion based on acute/chronic aquatic toxicity values as indicated in REACH Annex XIII (key studies, weight of evidence, supporting studies); (3) information on harmonised or self-classification of the substance for health effects resulting in meeting the T criterion; and (4) Furthermore, a new scenario has been developed to identify substances which are potentially toxic to soil–dwelling organisms. This information could be used in combination with the scenarios for octanol/air partition coefficient (KOA) which identify substances which potentially bioaccumulate in air-breathing organisms.

Experimental data

Different T-scenarios have been developed for separating the substances based on reported reliability of the study taken into consideration.

T-scenarios relying on experimental study results for aquatic toxicity endpoints are identifying substances based on values reported in the registration dossiers. It is proposed to use as cut-off values the following: for acute aquatic toxicity < 0.1 mg/L, for chronic aquatic toxicity < 0.01 mg/L. Scenarios are designed in a way that if the initial scenarios identify too few substances, the following scenarios will identify more substances. It is not possible to automatically distinguish between nominal or measured concentrations in the registration dossiers. This should be checked in the manual screening step.

For selection based on acute aquatic toxicity the lowest LC50 values among the test results for fish, invertebrates (preferably daphnia) and aquatic plants (algae) are taken into account.

For chronic toxicity the selection is based on the lowest NOEC/EC$_x$ value ($x \geq 10$) taking into account results for long term tests for fish, daphnia and algae.

The new scenario for terrestrial toxicity uses values reported in the registration dossiers. A cut-off value of EC1$_{0}$/NOEC < 6 mg/kg dw is used for all toxicity data on soil-dwelling organisms. Key studies, weight of evidence and supporting studies are all considered. The cut-off value is based on a JRC review of available criteria for non-aquatic organisms.

Information on harmonised or self-classification

When assessing T based on harmonised or self-classification for health effects, T is assumed if the substance is classified as one of the following: Muta. 1A,1B, Carc. 1A,1B, Repr. 1A,1B,2 or STOT RE 1,2.

5.2. Screening scenario logic: SVHC

The aim of the SVHC screening scenarios is to identify substances for which a full registration has been received and which contains a constituent, impurity or additive which is identical to a PBT or vPvB substances that is in the PBT pool of substances (e.g. Candidate List).

In addition for round 3 we propose to identify substances for which only registration as intermediate or C&L notifications have been received but where the substances are structurally similar to substances in the PBT RMO pool and Candidate List. This refers to supplementary activities under the SVHC Roadmap as further exemplified in Figure 4 and aim at identifying potential alternatives substances to those already subject to scrutiny by authorities.

6. Screening scenarios for Endocrine Disruptors

6.1. Logic of screening scenarios

The scenarios to identify suspected endocrine disruptors cover both environment and human health concerns. In order to keep the scenarios as transparent and understandable as possible,
some of the scenarios address only one of the two areas. This may at the begin of the manual screening phase also help to get an indication of the most obvious area of concern. Please note that there are no formal criteria for identification of EDs at the moment. Under REACH EDs are identified case by case based on the WHO/IPCS definition. According to the recommendation of the EU Commission's Endocrine Disruptor Expert Advisory Group (ED EAG), factors such as severity, irreversibility, lead toxicity and potency can be considered to characterise the hazard potential of an endocrine disrupting substance, e.g. when assessing the relevance of a substance for consideration in regulatory terms.

The scenarios to identify potential endocrine disrupting substances developed for screening can be broadly categorised into the following families:

- scenarios that check if the registered/notified substance itself, or a constituent, impurity or additive can be found in published lists of suspected endocrine disruptors or are structurally similar to substances in these lists
- scenarios that use models to check if the molecular structure of the registered/notified substance itself, and its constituents, impurities or additives triggers specific structural alerts for endocrine disruption
- scenarios that use the self- and harmonised classification suggesting suspected endocrine disruption effects, such as presence of specific target organ toxicity classifications for endocrine organs
- scenarios that analyse the information in the registration dossiers and chemical safety reports by looking for the presence of text patterns that are typically associated with evidence for/indications of endocrine disrupting properties
- scenarios that use positive findings in external experimental data generated with assays to identify possible endocrine disruption effects, such as USEPA ToxCast

The scenarios for suspected ED substances apply equally to CoRAP and SVHC with little differentiation, and cannot be used for identifying candidates for harmonised classification. The core activities of the SVHC Roadmap are proposed to focus on registered substances with uses subject to authorisation and to start first with those substances included in the Endocrine Active Substances Information System as category 1 or 2 EDs or in the Endocrine Disruption Exchange (TEDx) database. However, even for those substances manual screening will be needed to consider if there is sufficient information to make a decision for the ED properties. In case there is no sufficient information, then further information needs to be generated for the clarification of the ED properties, typically through Substance Evaluation and in some cases first via Compliance Check. There are no specific information requirements for endocrine disruption under REACH and at the moment there are no officially agreed EU criteria for identifying endocrine disrupters. Under REACH EDs are identified case by case based on the WHO/IPCS definition. According to the recommendation of the EU Commission's Endocrine Disruptor Expert Advisory Group (ED EAG), factors such severity, irreversibility, lead toxicity and potency can be considered to characterise the hazard potential of an endocrine disrupting substance, e.g. when assessing the relevance of a substance for consideration in regulatory terms. Hence, all scenarios developed so far provide hints towards this possibility, but no
scenario alone is considered sufficiently robust\textsuperscript{28} for selecting a substance for manual screening. Therefore, we propose that the ED scenarios are applied in a weight-of-evidence fashion, i.e. the identification of a registration for multiple reasons relying on different scenarios and parts of the registration dossier or the chemical safety report is expected to be more reliable than for a single piece of evidence, e.g. a structural alert. Although all scenarios have been marked as applicable to both CoRAP and SVHC, certain combination of scenarios are more suitable for one process than another and this aspect will be considered when compiling the short list of substances for manual screening.

The majority of scenarios apply to the registered/notified substance or to their constituents, and they will have priority for the selection of substances for manual screening. Nevertheless, there is a limited number of scenarios that apply to impurities and additives. They have been included in the screening to provide additional information if the substance is added to the short list for other reasons. For all scenarios, the algorithms use a concentration threshold of 0.1\% w/w or v/v.\textsuperscript{29}

Several scenarios attempt to identify endocrine disrupting evidence in unstructured parts of the IUCLID dossier or the chemical safety reports. These scenarios were developed by using as a guide the effects seen in registration dossiers for substances already submitted to Substance Evaluation due to their suspected endocrine disrupting properties. The set of effects to be looked for were encoded in text patterns (keywords or phrases) that were provided by Member State Competent Authorities as part of the consultation on previous screening rounds or identified internally by ECHA experts. Although every effort was made to select keywords and phrases that minimise the false positives, the nature of these scenarios implies that there could be registrations that are falsely identified. The input of the MSCAs and stakeholders is sought on further improving these scenarios by proposing more or better text patterns.

The scenarios in this definition document are focused on identifying substances that may be endocrine disruptors regardless of their exposure pattern. Additional non-hazard criteria need to be applied to determine the relevancy of the substance for Substance Evaluation or Risk Management (e.g. exposure considerations). These non-hazard criteria are described in chapter 3.

### 6.2. Scenarios based on molecular structures

Several of the scenarios check if the registered substance or one of its constituents, impurities or additives:

\textsuperscript{28} The implemented scenarios are technically robust and accurately reflect their technical description in Annex I. However, the subtle nature of the ED effects pose challenges in accurately identifying ED substances using algorithms, compared, for example, with other areas such as screening for PBT substances where more defined criteria exist (REACH Annex XIII).

\textsuperscript{29} The main reason why constituents and impurities are split in different scenarios is that constituents are expected to be identical in all registrations for the same substance (being constituents essential for the functioning of the substance), whilst the impurities can differ for the same substance (being impurities dependent on the manufacturing process). Please note that although constituents are typically found in higher concentrations than impurities, this is not always the case. In fact, depending on the type of registered substance, constituent and impurities can have different relevance. For mono constituent substances, impurities can have concentration ranges up to 20 \% w/w or v/v. On the other hand, there are no impurities for UVCB substances but constituents can be found at very low concentration. The exact concentration of the constituent, impurity or additive is included in the master list and will be used when creating the short list for manual screening and can considered by MSCAs when using the master list for other purposes.
are structurally identical to a suspected endocrine disruptor
- are structurally similar to a suspected endocrine disruptor; these scenarios are only applied if the substance, constituent, impurity or additive is not structurally identical to a suspected endocrine disruptor
- contain one of the structural alerts developed to identify substances that may have endocrine disruption properties
- are predicted to cause endocrine disruption effects in one or more of the predictive models used for screening

All these scenarios use molecular structures, but in a different way. The implementation of the fourth group of scenarios in the above list is straightforward. The algorithms generate molecular structures based on the identifiers provided in the registration dossiers and C&L notifications and then these molecular structures are used for running the predictive models. The first group of scenarios looks for chemical identity, i.e. the registered/notified substance or constituent is structurally identical to the substance in the list of suspected endocrine disruptors. The second group of scenarios require that the molecular structures are similar, i.e. they share the majority of atoms and connectivity but are not identical.30 The third group of scenarios require that the molecular structure of the registered/notified substance or constituent contains a given fragment (structural alert) often occurring in the structure of already confirmed endocrine disruptors.

Table 2 provides practical examples for the different cases.

**Table 2: Ways in which molecular structures were used in scenarios for identifying potential ED substances.**

*Note: This table only provides illustrative examples on what constitutes a similarity and substructure match and does not include real scenario results. The majority of ED scenarios use strict similarity threshold criteria.*

<table>
<thead>
<tr>
<th>Suspected endocrine disruptor in external list/structural alert</th>
<th>Registered/notified substance or constituent</th>
<th>Structurally identical</th>
<th>Structurally similar</th>
<th>Structural alert</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Molecule A" /></td>
<td><img src="image2.png" alt="Molecule B" /></td>
<td>yes</td>
<td>not applicable</td>
<td>matches (the fragment in red shows the matching part)</td>
</tr>
<tr>
<td><img src="image3.png" alt="Molecule C" /></td>
<td><img src="image4.png" alt="Molecule D" /></td>
<td>no</td>
<td>yes (low distance)</td>
<td>matches</td>
</tr>
</tbody>
</table>

30 Certain effects, such as endocrine disruption or reproductive toxicity, can be very sensitive to changes in molecular structure, and hence a difference in a critical part of the molecular structure, such as a hydrogen bond donor or acceptor, may significantly alter the activity. To reduce the occurrence of false positives, the algorithm uses strict thresholds for structural similarity. We note that in the future ECHA will complement structural similarity with structural alerts, i.e. structural similarity will only be computed if the two structures compared share the same structural alerts (e.g. using the QSAR Toolbox) for the endpoint the particular scenario refers to. This change will require redevelopment of a large number of scenarios and cannot be implemented at this stage.
### 6.3. Scenarios based on the search of keywords in the free text fields

Endocrine disruption is no adverse effect directly addressed by the REACH standard information requirements. However, an indication that a chemical may interfere with the endocrine system can be found in the registration dossiers under those endpoints reporting long term exposure effects:

- repeated dose toxicity,
- toxicity to reproduction,
- fertility and developmental toxicity
- long-term toxicity to fish, aquatic invertebrates and other aquatic organisms

and also in the section with the GHS self-classification if STOT RE classifications refer to endocrine organs.

It is important to stress that algorithms based on keywords can be very successful in identifying potential endocrine effects, even if these effects are not the ones that drive the DNEL derivation. However, these algorithms need to be accurately tuned to avoid false hits. The reliability of the scenarios depends on the complexity of the search pattern and also on the location of the information in the registration dossiers. For example, we can be fairly sure that if the registrant reports STOT RE classification that refers to an endocrine organ, such as the thyroid, then this organ has been adversely affected and hence the substance can be identified as likely to cause toxicity to endocrine organs. The same is true if endocrine organs are included in the basis for effect in the effect levels table of results of repeated dose endpoint
study records. Such keyword searches are generally robust and hence ECHA has included them in separate scenarios that are expected to be of high reliability.

Endocrine disruption evidence may also be reported in the registrant’s summary, conclusions or executive summaries. Typically, such effects are only reported and are not used in the chemical safety assessment, i.e. are not used in the DNEL derivation. Nevertheless, they are considered important for the purposes of screening. The challenge with such keyword searches is the fact that it not straightforward to algorithmically recognise whether the registrant reports adverse effects, or simply refers to parameters of the test related to endocrine disruption without necessarily providing any evidence for adverse effects. Hence, it is necessary to follow a more complex search strategy. ECHA proposes to concatenate all free fields where endocrine disruption effects may be reported (separately for human health and environment) and then split the text in sentences. A dossier will be identified as likely to report endocrine disruption findings if there is one or more sentence that satisfies all of the following:

- the sentence contains a ED term that describes an organ or test parameter related to the endocrine system, such as “thyroid weight”
- the sentence contains a modifier term, such as “increase” or “abnormal”
- the sentence does not contain a negation

As an illustration, the table below provides some examples with the ED term “hormone” and different modifiers:

<table>
<thead>
<tr>
<th>Sentence in free field</th>
<th>Hit</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes in hormone levels were observed.</td>
<td>Y</td>
<td>The scenario is triggered because an ED keyword (“hormone”) and a modifier (“changes”) are present in the same sentence without any negation.</td>
</tr>
<tr>
<td>Hormone levels were normal.</td>
<td>N</td>
<td>The scenario is not triggered because of the lack of a modifier in the sentence.</td>
</tr>
<tr>
<td>No changes in hormone levels were observed.</td>
<td>N</td>
<td>The scenario is not triggered because of the presence of a negation.</td>
</tr>
</tbody>
</table>

For all scenarios following this search strategy, ECHA intends to refine the scenarios by generating results using the algorithms, discussing the results with ECHA’s ED experts and iterating the input files with the used ED terms, modifiers and patterns to detect negations until satisfactory results are obtained.
6.4. Scenarios based on in-vitro ToxCast HTS data

These scenarios are based on the results of the US EPA’s ToxCast HTS assays for estrogen, androgen, steroidogenic and thyroid disrupting mechanisms. The aim is to flag compounds positive in these ED-related in-vitro HTS assays.

The US EPA’s ToxCast Program seeks to use high-throughput, in-vitro biological assays to characterize potential health hazards of chemicals for use in chemical prioritization for more in-depth study. The results of these in-vitro HTS assays could also be used to identify potential endocrine disrupting chemicals. The US EPA’s ToxCast Program provides data for 1861 chemicals and 342 assays. Out of these 342 assays, of which some are ED-related. Four pathways have been identified and related scenarios have been developed according to the pathway, i.e. androgenic, estrogenic, steroidogenic, and thyroid-related.

6.5. Scenarios based on the DK QSAR models

Scenarios based on QSAR models developed by the Danish QSAR group at DTU Food have been introduced in common screening. The QSAR models have been implemented in the modelling platform Leadscope and attempt to predict several modes of action related to endocrine disruption. Depending on the predicted ED mechanism and whether the predictions refer to the registered substance or part of the composition (constituents, impurities or additives), the models have been categorised in different scenarios in a similar fashion to the categorisation of scenarios based on ToxCast data. All of these models require pre-processing of the molecular structures to ensure that predictions are only used for molecular structures that are structurally acceptable for QSAR processing.

In particular, the following pre-processing/filtering of molecular structures is carried out:

- molecular structures that are not discrete organics are not subject to predictions
- molecular structures that do not contain at least two carbon atoms are not subject to predictions
- molecular structures with atoms other than H, Li, B, C, N, O, F, Na, Mg, Si, P, S, Cl, K, Ca, Br and I are not subject to predictions
- molecular structures that correspond to mixtures or salts are not subject to predictions, unless if the salt is formed by an organic part and a small counter ion that is not expected to affect the observed toxicity, such as Na+ salts

In the case of salts that are acceptable for processing, the small counter ion that is not expected to affect toxicity is stripped off prior to running the predictions.
7. Exclusion criteria

The first step before short listing substances based on hazard and non-hazard (exposure related and structural similarity) criteria is to exclude those substances where for instance work has already been initiated. Generic and specific exclusion criteria are further defined in this section.

7.1. Generic exclusion criteria

As described in Section 2.3, the starting pool comprises all substances for which ECHA has received a registration or a C&L notification, and also NONs for which ECHA has not yet received an updated REACH dossier. Before any of the scenarios are applied, we apply the following generic exclusion criteria for all hazard areas:

- All registrations for substances in any of the previous or current CoRAP lists
- All registrations for substances that have been manually screened in previous rounds of common screening in the last 3 years (if a substance has been in the short list but not selected for manual screening, then the substance may be short listed again, but there will be an administrative warning informing about the previous short listing)
- All registrations for substances in the Concawe inventory
- All registrations for petroleum substances, coal derivatives and oil distillates or substances containing an assessment based on petrotox/petrorisk
- Irreversibly ceased registrations
- Annulled registrations

7.2. Specific exclusion criteria

7.2.1. Hazard area related exclusion criteria (regardless of process)

A registration is excluded for a given hazard area, if there is an ongoing testing proposal or compliance check on an endpoint directly related to the suspected concern. For example, we will exclude registrations with ongoing compliance check on mutagenicity for substance evaluation metascenarios that attempt to find substances with inconclusive/likely mutagenic substances. Similarly, if the suspected concern is endocrine disruption for human health, but there is a pending testing proposal for a fertility study, the registration will be excluded until the test results are available. Once the test has been conducted and an updated registration has been received, the registration dossier will be once more subject to screening.

Specific exclusion criteria are further specified for each hazard area below.

7.2.1.1. Human health

Substances that fulfil one or more of the following criteria are excluded from all HH scenarios if the substances are included in those different lists because of their HH properties:

- The substance is in the candidate list if the scope includes CMR, sensitising and/or STOT RE properties
• There is an intention or pre-intention to prepare an Annex XV dossier for identification as SVHC or Restriction if the scope includes CMR, sensitising and/or STOT RE properties
• Screening or RMO analysis is on-going or has been carried out and follow-up activity is indicated to be related to CMR, sensitisation or STOT RE

7.2.1.2. Environment

Substances that fulfil one or more of the following criteria are excluded from all ENV scenarios if the substances are included in those different lists because of their PBT properties:

• The substance is in the candidate list if the scope includes PBT properties;
• There is an intention or pre-intention to prepare an Annex XV dossier for identification as SVHC or Restriction if the scope includes PBT;
• Screening or RMO analysis is on-going or has been carried out and follow-up activity is indicated to be related to PBT;
• The substance is listed in the Stockholm Convention as a POP;
• The substance is included in the PBT EG working list and the assessment is ongoing or concluded;
• The substance is an inorganic substance

7.2.1.3. ED

Substances that fulfil one or more of the following criteria are excluded from all ED scenarios if the substances are included in those different lists because of their ED properties:

• The substance is in the candidate list
• There is an intention or pre-intention to prepare an Annex XV dossier for identification as SVHC or Restriction
• Screening or RMO analysis is on-going or has been carried out
• The substance is listed in the Stockholm Convention as a POP

7.2.2. Process related exclusion criteria (regardless of hazard area)

For Substance Evaluation, and regardless of the hazard area, only substances for which full REACH registrations exist will be short listed. In addition the following substances will be excluded for Substance Evaluation:

• The substance was evaluated under the ESR program in the past
• The substance is an existing substance being subject to transitional measures

7.2.3. Exclusion criteria related to a particular hazard area and process

For Substance Evaluation, registrations with harmonised classification as carcinogen (1A or 1B), mutagen (1A or 1B) or toxic for reproduction (1A or 1B) are excluded.

[1] Organic impurities and/or additives may have PBT/vPvB properties but this will not be considered in this screening but may be considered later.
31 Unless substance of concern for terrestrial ecosystems
8. Short listing criteria

The section below describes the short listing criteria for the different hazard and non-hazard areas. These criteria, in combination with the administrative information and exclusion criteria will be used for constructing the final short list. We note that from round 3 onwards, ECHA is working closely with the Evaluation teams processing the Compliance Check follow up cases. Some of these cases may need to be introduced in the short list manually if the additionally provided information suggests that further regulatory action may be necessary.

In Round 4, substances have also been included based on a grouping approach. These substances have not been identified as such based on one of the screening scenarios developed in the definition document but have been found to be similar or grouped with one of the substances identified and shortlisted based on screening scenarios. This “grouping approach” is based on structural similarity (using the generated molecular structures) as shortly described in section 3.7 of this document, proposed read across and categories under REACH registration dossiers or other regulatory regimes (e.g. IMAP, OECD).

8.1. Non-hazard short list criteria

A single short list will be prepared for the three REACH and CLP processes (SVHC, CoRAP and CLH), using the same criteria. Substances to be selected for manual screening are those where both hazard and non-hazard triggers are fulfilled. Non-hazard criteria are exposure and used based, but structural similarity is also used for SVHC supplementary activities.

When selecting substances for shortlisting, lists are generated based on IT pre-selection and very little further manual intervention is performed. In consequence, a first selection of substances is made on the basis of environment, ED, and human health criteria as described in the corresponding sections of this document. Starting from that selection, substances are further selected using the non-hazard criteria that are described here below.

Exposure related non-hazard metascenarios combining screening indicators and scenarios have been used to select substances for the short list relevant for all processes (SVHC, CoRAP and CLH). These metascenarios have been applied on the pool of substances selected based on hazard scenarios further described in section 4 regarding human health, section 5 regarding environment and section 6 for ED properties.

As it is difficult to anticipate the number of candidates available after applying the exposure related non-hazard scenarios, a tiered approach has been developed and applied when short listing. This is further developed in this section.

In addition, for SVHC supplementary activities using structural similarity as non-hazard scenario the approach is further developed in section 8.1.2.

8.1.1. Exposure related non hazard criteria for preparation of the short lists

Substances will first be short listed based on short list hazard criteria developed respectively in section 4 for HH, section 5 for ENV and section 6 for ED.
Those substances will be further prioritised using the non-hazard criteria following a tiered approach. The tiered approach that has been developed and applied when short listing comprises successive tiers that are increasingly restrictive:

- **Tier 1**: 1 widespread use metascenario common to HH, ENV, ED pool of substances
- **Tier 2**: three wide dispersive use metascenarios specific to HH, ENV and ED pool of substances. The substances selected in Tier 2 are those having at least one single use which is BOTH widespread and having a potential for exposure/release.
- **Tier 3**: substances obtained using tier 1 or 2 are ranked by using the “Sum of average total use tonnage at substance level” covering all registration dossiers (full and intermediates)
- **Tier 4**: substances from tier 1 or 2 are ranked by using the “Sum of average total use tonnage at substance level” covering only full registration dossiers (Article 10)

### 8.1.1.1. Tier 1 Metascenario (widespread use)

<table>
<thead>
<tr>
<th>Initial concern</th>
<th>Metascenario Name</th>
<th>Metascenario definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>HH, ENV or ED</td>
<td>Widespread use</td>
<td>Registered AND Substance in the Authorisation/SEv scope, AND Widespread use</td>
</tr>
</tbody>
</table>

### 8.1.1.2. Tier 2 Metascenarios (widespread, wide dispersive for the same use)

<table>
<thead>
<tr>
<th>Initial concern</th>
<th>Metascenario Name</th>
<th>Metascenario definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Health</td>
<td>Wide dispersive use (HH)</td>
<td>Registered AND Substance in the Authorisation/SEv scope, AND (Widespread use as defined in Tier 1 AND Potential for exposure, for the same use)</td>
</tr>
<tr>
<td>Environment</td>
<td>Wide dispersive use (ENV) (1)</td>
<td>Registered AND Substance in the Authorisation/SEv scope, AND (Widespread use AND Potential for release, for the same use)</td>
</tr>
<tr>
<td>ED</td>
<td>Wide dispersive use (ED) (2)</td>
<td>Substance in the SVHC scope, AND (Widespread use AND Potential for exposure OR potential for release, for the same use)</td>
</tr>
</tbody>
</table>

(1) That metascenario cannot be presently technically implemented because it requires a matching between the uses typology in REACH and the typologies used in SPIN and CDR databases, and this does not exist presently.

(2) For the same reason, that metascenario cannot be implemented for the environment aspects; it has been implemented for the human health aspects.

### 8.1.1.3. Tier 3 Metascenarios (tonnages, including intermediates)
<table>
<thead>
<tr>
<th>Initial concern</th>
<th>Metascenario Name</th>
<th>Metascenario definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>HH, ENV or ED</td>
<td>Tonnage (full + intermediates)</td>
<td>Rank substances obtained with Tier 1 metascenarios and select amongst the highest</td>
</tr>
</tbody>
</table>

### 8.1.1.4. Tier 4 Metascenarios (tonnages, full registrations only)

<table>
<thead>
<tr>
<th>Initial concern</th>
<th>Metascenario Name</th>
<th>Metascenario definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>HH, ENV or ED</td>
<td>Tonnage (only full registration)</td>
<td>Rank substances obtained with Tier 1 metascenarios and select amongst the highest</td>
</tr>
</tbody>
</table>

### 8.1.2. Non-hazard criteria: structural similarity

Figure 1 illustrates where structural similarity is used as a non-hazard criterion. Structural similarity is used as a non-hazard criterion on substances screened as being structural similar to one of the substance in the (hazard) pool for RMOA (in the Registry of intention, for which a RMOA is on-going or has been submitted or in the Candidate List) and for which there is only registration as intermediate and/or a C&L notification (SVHC Roadmap supplementary activities). For those substances the exposure related non-hazard criteria are not used.

### 8.2. Human health short list criteria

#### 8.2.1. CoRAP

The short list for SEv substances were derived using a combination of scenarios that examined the self-classification provided by the registrant, the presence of harmonised classification and the presence of hazard information in the registration dossier. The following meta-scenarios were used as starting points:

- Substances show high toxicity (Low NOAEL/LOAEL) and adverse effects on fertility indicated in a registration,
- Substances show high toxicity (Low NOAEL/LOAEL) and adverse effects on pre-natal development indicated in a registration

The results were further refined using the non-hazard criteria defined in section 8.1.1., see also below.

**Short listing strategy for round 4**

<table>
<thead>
<tr>
<th>Trigger for concern</th>
<th>Detailed Description</th>
<th>Non-hazard tier applied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity</td>
<td>Substance shows high toxicity (Low NOAEL/LOAEL) and adverse effects on fertility indicated in a registration</td>
<td>Tier I and Tier III (≥100t)</td>
</tr>
</tbody>
</table>
### 8.2.2. Risk Management

#### 8.2.2.1. SVHC

Substances with the harmonised classification as CMR category 1A/1B, respiratory and skin sensitisation and STOT RE are relevant from an SVHC identification point of view (Art. 57 of the REACH Regulation). In addition, any substance containing a substance with a harmonised classification in these hazard classes as an impurity, additive or a constituent can also be relevant for SVHC identification.

Extensive work has been carried out on substances with harmonised classification over the years therefore it is expected that the actual candidates for this round and future rounds will be very few even though the CLP Annex VI list is updated every year according to the latest applicable ATP which could lead to some additional hits. For Round 4 of shortlisting, we used the version of Annex VI up to the 6th ATP.

**Shortlisting strategy for Round 4:**

**Core Activities under the SVHC Roadmap:**

<table>
<thead>
<tr>
<th>Trigger for concern</th>
<th>Description</th>
<th>Non-hazard tier applied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity</td>
<td>Substance shows high toxicity (Low NOAEL/LOAEL) and adverse effects on pre-natal development indicated in a registration</td>
<td>Tier I and Tier III(≥100t)</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>The registered substance has a harmonised classification as Carc. 1A/1B</td>
<td>Tier I</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>The registered substance has a harmonised classification as Muta. 1A/1B</td>
<td>Tier I</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>The registered substance has a harmonised classification as Repr. 1A/1B</td>
<td>Tier I</td>
</tr>
<tr>
<td>Respiratory sensitisation</td>
<td>The registered substance has a harmonised classification as Resp. Sens 1/1A/1B</td>
<td>Tier I</td>
</tr>
<tr>
<td>STOT RE</td>
<td>The registered substance has a harmonised classification as STOT RE 1</td>
<td>Tier I</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>At least one registration reports a constituent that is a harmonised carcinogen (category 1A/1B).</td>
<td>Tier I</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>At least one registration reports a constituent that is a harmonised mutagen (category 1A/1B).</td>
<td>Tier I</td>
</tr>
<tr>
<td>Trigger for concern</td>
<td>Description</td>
<td>Non-hazard tier applied</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>At least one registration reports a constituent that is a harmonised reproductive toxicant (category 1A/1B)</td>
<td>Tier I</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>At least one registration reports an impurity that is a harmonised carcinogen (category 1A/1B), above the specific or generic concentration limits.</td>
<td>Tier I</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>At least one registration reports an impurity that is a harmonised mutagen (category 1A/1B), above the specific or generic concentration limits.</td>
<td>Tier I</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>At least one registration reports an impurity that is a harmonised reproductive toxicant (category 1A/1B), above the specific or generic concentration limits.</td>
<td>Tier I</td>
</tr>
</tbody>
</table>

For core activities under the SVHC Roadmap (see section 4.3), substances with a harmonised classification as CMR category 1A/1B, respiratory sensitisation and/or STOT RE 1 were selected. In addition, substances where at least one registration reported a constituent or an impurity with a harmonised CMR category 1A/1B classification above the generic or specific concentration limits were also selected.

The results were further refined using the non-hazard criteria defined in section 8.1.1. For all of the metascenarios, the widest possible non-hazard tier (Tier I) was selected.

**Supplementary Activities under the SVHC Roadmap**

In previous rounds, individual substances for supplementary activities for the SVHC Roadmap were identified by combining either a harmonised or self-classification for critical endpoints (e.g. CMR) and structural similarity to substances already identified as SVHCs. For Round 4, substances for supplementary activities were identified using a grouping approach. Registered or notified substances that are structurally similar to substances on the Candidate List were identified and grouped together based on similarity, read-across or categories. As a pilot exercise, two defined groups with several substances on the Candidate List and several identified substances either registered or notified were shortlisted. The two pilot groups were phthalates and glycol ethers.

**8.2.2.2. CLH**

Substances fulfilling the criteria for carcinogenicity, mutagenicity, reproductive toxicity and/or respiratory sensitisation should normally be subject to harmonised classification and labelling (Art. 36 of the CLP Regulation). Substances fulfilling criteria for other hazard classes may also be harmonised, if a justification demonstrating the need for Community level action is provided. The scenarios developed primarily aim at identifying new CMR and RS substances, not currently harmonised, as well as identifying substances of potential concern for the SVHC process.

**Short listing strategy for round 4:**
### Screening definition document

<table>
<thead>
<tr>
<th>Trigger for concern</th>
<th>Description</th>
<th>Non-hazard tier applied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity</td>
<td>The substance is classified as a carcinogen (categories 1A, 1B or 2) by at least one REACH registrant and does not have a harmonised classification for that hazard class</td>
<td>Tier I</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>The substance is classified as a mutagen (categories 1A, 1B or 2) by at least one REACH registrant and does not have a harmonised classification for that hazard class</td>
<td>Tier I</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>The substance is classified as a reproductive toxicant (categories 1A, 1B or 2) by at least one REACH registrant and does not have a harmonised classification for that hazard class</td>
<td>Tier I</td>
</tr>
<tr>
<td>Respiratory sensitisation</td>
<td>The substance is classified as a respiratory sensitiser by at least one REACH registrant and does not have a harmonised classification for that hazard class</td>
<td>Tier I</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>The substance has been identified as a known, presumed or suspected carcinogen in the IMAP, IARC and/or RoC assessment lists and does not have a harmonised classification for that hazard class</td>
<td>Tier I</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>The substance has been identified as a known, presumed or suspected mutagen in the IMAP assessment list and does not have a harmonised classification for that hazard class</td>
<td>Tier I</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>The substance has been identified as a known, presumed or suspected reproductive toxicant in the IMAP assessment list and does not have a harmonised classification for that hazard class</td>
<td>Tier I</td>
</tr>
<tr>
<td>Respiratory sensitisation</td>
<td>The substance has been identified as a known, presumed or suspected respiratory sensitiser in the IMAP assessment list and does not have a harmonised classification for that hazard class</td>
<td>Tier I</td>
</tr>
</tbody>
</table>

In order to identify CLH candidates for Round 4, two approaches were used. The first examined the classification reported in the REACH registration dossiers. When at least one REACH registrant (regardless of type of registration) classified the substance for CMR or RS in any category, the substance was included. For C, M and RS, only Tier I of the non-hazard criteria (see section 8.1.1) was applied but for reproductive toxicity, both Tier II and Tier III were applied.

The second approach was to examine external lists and evaluations made by other bodies or national authorities. The lists used for this round were:

The 13th Report on Carcinogens (RoC) published by the US National Toxicology program (http://ntp.niehs.nih.gov/pubhealth/roc/roc13/index.html).

### 8.3. Environment short list criteria

#### 8.3.1. CoRAP criteria

Criteria for CoRAP shortlisting rely on scenarios that take into account:

- registrant statements for PBT, vPvB, P, B, and T;
- harmonised or self-classification for T;
- experimental data available in the dossiers for P, B, and T (including terrestrial toxicity data);
- estimations and modelling predictions for P;
- additional information (external databases and model predictions) for B
- non-hazard criteria (widespread use, tonnage).

The scenario combinations used for short-listing are listed in the table below.

**Short listing strategy for round 4:**

<table>
<thead>
<tr>
<th>Trigger for concern (terrestrial endpoints)</th>
<th>Detailed description</th>
<th>Non-hazard tier</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBT</td>
<td>Suspected PBT properties for the substance based on experimental data, modelling predictions, external databases, and/or harmonized/self-classification for toxicity.</td>
<td>Tier I and Tier III(≥10t)</td>
</tr>
<tr>
<td>PB</td>
<td>Suspected persistence and bioaccumulation properties for the substance based on experimental data and modelling predictions.</td>
<td>Tier I and Tier III(≥500t)</td>
</tr>
<tr>
<td>PBT concern</td>
<td>Substance shows suspected persistence, potential for terrestrial bioaccumulation (based on experimental phys-chem data and modelling predictions), and toxicity for terrestrial invertebrates, plants, and/or microorganisms (based on experimental data).</td>
<td>Tier I and Tier III(≥10t)</td>
</tr>
</tbody>
</table>

#### 8.3.2. SVHC criteria

No criteria have been used for identifying potential SVHC this year as already last year the number of potential candidates was very limited.
8.4. ED short Listing Criteria

This section provides the particular combination of scenarios (called meta-scenarios) for creating the short list with regard to substances with likely ED properties.

8.4.1. CoRAP criteria

The scenarios for endocrine disruption are less determinative than the scenarios for human health or environment based on established thresholds, such as e.g. those in REACH Annex XIII for PBT substances. Hence, we consider that the use of scenarios in a weight of evidence mode (i.e. ED meta-scenarios) will increase the probability that the substances identified by the algorithms are EDs.

Short listing for CoRAP with regard to ED concern has been carried out by using these scenarios in combination with the non-hazard tier I meta-scenarios.

Preference for shortlisting has been given to reference substances and constituents over impurities and additives.

**Short listing strategy for round 4:**

<table>
<thead>
<tr>
<th>Trigger for concern</th>
<th>Detailed description</th>
<th>Non-hazard tier</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED</td>
<td>The substance or a constituent is listed as (suspected) endocrine disruptors in external list(s) (Commission, WHO, TEDX or SIN) AND it is predicted as potential ED by QSAR models</td>
<td>Tier 1</td>
</tr>
<tr>
<td>ED</td>
<td>The substance or a constituent is listed as (suspected) endocrine disruptors in external list(s) (Commission, WHO, TEDX or SIN) AND it is reported to be (or similar to) a developmental and reproductive toxicant in the DART database</td>
<td>Tier 1</td>
</tr>
<tr>
<td>ED</td>
<td>The substance or a constituent is listed as (suspected) endocrine disruptors in external list(s) (Commission, WHO, TEDX or SIN) AND it is positive in at least one of the ToxCast in vitro assays related to ED</td>
<td>Tier 1</td>
</tr>
<tr>
<td>ED</td>
<td>The registered substance or any constituents are similar to a substance listed as suspected endocrine disruptors in public lists (Commission, WHO, TEDX or SIN) AND it is predicted as potential ED by QSAR models</td>
<td>Tier 1</td>
</tr>
<tr>
<td>Trigger for concern</td>
<td>Detailed description</td>
<td>Non-hazard tier</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>ED</td>
<td>The registered substance or any constituents are similar to a substance listed as suspected endocrine disruptors in public lists (Commission, WHO, TEDX or SIN) AND it is reported to be (or similar to) a developmental and reproductive toxicant in the DART database</td>
<td>Tier 1</td>
</tr>
<tr>
<td>ED</td>
<td>The registered substance or any constituents are similar to a substance listed as suspected endocrine disruptors in public lists (Commission, WHO, TEDX or SIN) AND it is positive in at least one of the ToxCast in vitro assays related to ED</td>
<td>Tier 1</td>
</tr>
<tr>
<td>ED</td>
<td>The substance has a harmonised classification, or a self-classification by at least one registrant, as both reproductive toxicant category 2 and carcinogen category 2</td>
<td>Tier 1</td>
</tr>
<tr>
<td>ED</td>
<td>The registered substance or any constituents are positive in at least one of the ToxCast in-vitro assays related to ED and predicted as potential ED by QSAR models</td>
<td>Tier 1</td>
</tr>
<tr>
<td>ED</td>
<td>There is evidence in a registration dossier study indicating ED related effects in (eco)toxicological studies AND registered substance or any constituents are identical or similar to a substance listed as suspected ED or reproductive toxicant in public lists (Commission, WHO, TEDX, SIN lists or DART database).</td>
<td>Tier 1</td>
</tr>
</tbody>
</table>

The application of the above mentioned scenarios led to the selection of more than 100 substances. To reduce this number, we ranked the substances according to the total tonnage for full registrations and selected the top 75.

### 8.4.2. SVHC criteria

For shortlisting substances for direct SVHC identification, we need to rely on scenarios that can identify substances for which the ED hazard assessment can be carried out without the need for additional data generated via Substance Evaluation. The scenarios that seem to be most suitable for this purpose look for exact matches of the substance itself or of a constituent with substances for which regulatory actions have been taken or are considered because of their ED properties (i.e. the substances in the “ED pool of substances”). In such cases the same conclusions on the hazard properties can be drawn as for their correspondents in the “ED pool of substances”. For reference substances or constituents similar to a substance in the “ED pool
of substances” read across may be possible but also chances are high that for concluding on the ED properties generation of further information would be required.

The “ED pool of substances” comprises the following:

- substances that have been included in the candidate list because of their ED properties,
- substances for which ECHA has received an intention for SVHC identification because of ED properties, and
- substances for which ECHA has received an intention to prepare an RMO because of ED properties.

---

**Figure 5 Screening and Identifying endocrine disruptors in the SVHC Roadmap implementation plan**

Shortlisting of substances for SVHC will be primarily based on identifying reference substances or constituents identical or similar to a substance included in the "ED pool of substances".

**Short listing strategy for round 4:**

<table>
<thead>
<tr>
<th>Trigger for concern</th>
<th>Detailed description</th>
<th>Non-hazard tier</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

*Initial focus on substances listed in the ED database (Endocrine Active Substances Information System)*
*The prioritisation for EDs and/or EDs may need to be carried out on a case-by-case basis under consideration of other priorities*
<table>
<thead>
<tr>
<th>Trigger for concern</th>
<th>Detailed description</th>
<th>Non-hazard tier</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED (SVHC Core activities)</td>
<td>The registered substance or any constituents is in ECHA’s candidate list because of ED properties or there is an intention for SVHC identification/RMOA preparation for ED properties</td>
<td>Tier 1</td>
</tr>
<tr>
<td>ED (SVHC Core activities)</td>
<td>The registered substance or any constituents is similar to a substance in the candidate list because of ED properties or ECHA has received an intention for SVHC identification/RMOA preparation for ED properties</td>
<td>Tier 1</td>
</tr>
<tr>
<td>ED (SVHC supplementary activities)</td>
<td>The registered substance or any constituents is in ECHA’s candidate list because of ED properties or there is an intention for SVHC identification/RMOA preparation for ED properties</td>
<td>No full registration available but at least one registration as intermediate OR existing assessment under other programmes</td>
</tr>
<tr>
<td>ED (SVHC supplementary activities)</td>
<td>The registered substance or any constituents is similar to a substance in the candidate list because of ED properties or ECHA has received an intention for SVHC identification/RMOA preparation for ED properties</td>
<td>No full registration available but at least one registration as intermediate AND an existing assessment under other programmes</td>
</tr>
</tbody>
</table>

The meta-scenarios applied for shortlisting SVHC substances for supplementary activities are the same as the one of the core activities from the hazard perspective, but they were applied on substances for which ECHA has received a registration dossier for intermediates or a notification but not (yet) a full registration. Given the high number of substances selected for supplementary activities with these scenarios (around 100) further non-hazard criteria were applied as described in the table above.
Appendix A SPIN database exposure indexes

The **use index** gives an indication of the worst case potential exposure of different recipients. The index is only based on the product register information "Industrial use" and "Use category" (of the mixture). Since no chemical/physical properties are integrated the exposure estimate is limited to the environment near the release source ("primary recipients"). Four environmental compartments are considered, "Surface water", "Air", "Soil", "Sewage treatment Plant". The index is presented per Nordic country. The following worst case assumption was used: When a substance is used in several uses with different exposure potential the index for the most critical usages per environmental compartments (target groups) are selected. Further, the specific quantities used are not considered. The Use index has been divided in the following categories:

<table>
<thead>
<tr>
<th>Use Index category</th>
<th>Use Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>One or several uses indicate a very probable exposure</td>
<td>5</td>
</tr>
<tr>
<td>One or several uses indicate a probable exposure</td>
<td>4</td>
</tr>
<tr>
<td>One or several uses indicate a potential exposure</td>
<td>3</td>
</tr>
<tr>
<td>The registered use do not indicate direct exposure</td>
<td>0 - 2</td>
</tr>
</tbody>
</table>

The **range of use index** indicates the broadness of the use of a substance in a Nordic country. It is based on the product register information "Industrial use" and "Use category". Each product is categorized in one or several codes describing their use category and the industry category of the user. The measured parameter for the index is the number of unique combination of use category and industry category per substance and country. The Range of Use index is presented in SPIN in the following categories:

<table>
<thead>
<tr>
<th>Range of Use categories</th>
<th>Application</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very wide range of applications</td>
<td>&gt; 100</td>
<td>*****</td>
</tr>
<tr>
<td>Wide range of applications</td>
<td>33-100</td>
<td>****</td>
</tr>
<tr>
<td>Intermediate range of applications</td>
<td>11-32</td>
<td>***</td>
</tr>
<tr>
<td>Narrow range of applications</td>
<td>3-10</td>
<td>**</td>
</tr>
<tr>
<td>Very narrow range of applications</td>
<td>&lt;3</td>
<td>*</td>
</tr>
</tbody>
</table>

The **Article Index** indicates if a substance is used in production of articles/goods. Each registered product is categorized with use descriptors. The Article Index is based on the use descriptors "Use Category" and "Industrial Category" (see above).

Worst case assumption: When a substance is used in several uses with different exposure potential, the index for the most critical usages per target group are selected.

The Article index has been divided in the following categories:

<table>
<thead>
<tr>
<th>Article Index categories</th>
<th>Article Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>One or several uses indicate a:</td>
<td></td>
</tr>
<tr>
<td>...very probable use in article productions</td>
<td>3</td>
</tr>
<tr>
<td>...probable use in article productions</td>
<td>2</td>
</tr>
<tr>
<td>...potential use in article productions</td>
<td>1</td>
</tr>
</tbody>
</table>
Appendix B Chemical Data Reporting (CDR) database

So far it has not been technically possible to add exposure information from CDR by creating a set of exposure scenarios similar to the ones developed for SPIN. However, ECHA intends to do so in the near future. This Appendix contains information on the structure of the CDR database that will form the basis for these additional scenarios.

B.1. Introduction
The Chemical Data Reporting (CDR) data were released in February 2013 and contain import, manufacturing, processing and use data for 2011 and production volume data for 2010. These data only cover chemical production and use in the U.S and are collected every four years with the next collection year being probably in 2016. The rule requiring the submission of CDR data is formally known as Inventory Update Reporting rule. The CDR data are used by US-EPA for risk screening, assessment, priority setting and management activities and will also be used by ECHA, in combination with registration and SPIN data for prioritisation purposes in the context of Substance Evaluation and Risk Management activities. EPA often performs periodic extractions of the data and posts updated versions of the database to the CDR website, which means that the data we are using in our processes should be refreshed more often than once in four years.

Last access time of CDR material and data analysis was done is on 26 June 2013 by Panos Karamertzanis. The starting website for this analysis is http://epa.gov/cdr.

B.2. How many and which chemicals are included
Full manufacturing data for 2011 and production volume for 2010 are only reported for chemicals when 2011 site-specific production volume equalled or exceeded 25 000 lb. Processing and use data for 2011 are reported only if the site-specific production volume for 2011 equalled or exceeded 100 000 lb. CDR contains data for 7674 chemicals submitted from 1528 companies. The number of reported sites is 4753. Process and use information is available for 5647 chemicals.

B.3. Kind of information found in CDR
CDR contains the following data:

1. 2010 and 2011 annual production (including import) volume for each reportable chemical and additionally the volume used on site, volume exported and whether the chemical is recycled, and

2. full processing and use data for 2011 when the site-specific volume is >= 100 000 lb/y

The production volume information also includes information on the number of workers that are reasonably likely to be exposed to each reportable chemical at each site. This information is reported in ranges, i.e. (<10 that is the lowest number possible to report, 10=< and < 25, .., >= 10 000). Finally, the production volume includes information on the tonnage used at the site, the tonnage directly exported and, hence, we can deduce the tonnage used for downstream processing. The manufacture information also includes the percentage for each physical form at the time it is reacted or is leaving the site.

The processing and use data include the following:
- processing or use operation descriptions, that can be processing as a reactant, incorporation into formulation, incorporation into article, repackaging or use in non-incorporative activities,
- for industrial uses, the industrial sector for all sites that received the chemical directly or indirectly from the manufacturer or importer and use the chemical, that can be, for
example, wood product manufacturing, or computer and electronic product manufacturing,

- for industrial uses, the industrial function category, that can be, for example, adhesives and sealant chemicals or adsorbents and absorbents,
- for consumer and commercial uses, the product category that can be, for example, floor coverings or laundry and dishwashing products. These product categories are grouped in families, such as chemical substances in automotive, fuel, agriculture, outdoor use products or substances in construction, paint, electrical and metal products.

For industrial uses, the combination of a processing or use operation, the industrial sector and the industrial function category form an “exposure scenario”. This information is combined with the percentage of the production volume associated with this use, the number of sites and the number of workers.

For consumer and commercial uses, the uses contain a flag showing if the use is commercial or consumer, a flag indicating whether the chemical is used in products intended for children, the per cent of the production volume associated with the use, the maximum concentration and the number of commercial workers being exposed.

In CDR, consumer use means the use of a chemical or a mixture containing a chemical (including as part of a manufactured item, or article, such as furniture or clothing) when sold or made available to consumers. Commercial use means of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise, such as dry cleaning. Industrial use means use at a site at which one or more chemicals or mixtures are manufactured or processed. Industry is required to report per site and submission may contain information for multiple chemicals. This has implications on the way the data need to be aggregated for screening activities.

The description of uses under CDR is explained in appendix D of the 2012 CDR instructions available at [http://www.epa.gov/cdr/tools/InstructionsManual.013112.pdf](http://www.epa.gov/cdr/tools/InstructionsManual.013112.pdf). Approximately 11% of the information in CDR is confidential and is not available to ECHA at present; most of this confidential information refers to domestic production and import volume. Only 3% of confidential business information in CDR refers to chemical identity and 6% to processing and use information, which means that this limitation will not have a major impact to ECHA’s screening activities.

The data found in CDR are summarised in the table below.

<table>
<thead>
<tr>
<th>CDR element</th>
<th>number</th>
</tr>
</thead>
<tbody>
<tr>
<td>total number of submissions (one per site)</td>
<td>4753</td>
</tr>
<tr>
<td>number of companies</td>
<td>1528</td>
</tr>
<tr>
<td>number of distinct sites</td>
<td>4753</td>
</tr>
<tr>
<td>number of distinct chemicals</td>
<td>7674</td>
</tr>
<tr>
<td>number of distinct chemicals manufactured in U.S.</td>
<td>5098</td>
</tr>
<tr>
<td>number of distinct chemicals imported in U.S.</td>
<td>3561</td>
</tr>
</tbody>
</table>
**B.4. Information from CDR that will be used in ECHA’s screening activities**

The CDR data model was carefully analysed and integrated within our screening machinery. As of June 2013, we found that from 8873 lead and individual registrations, there are US exposure data for 3255 using the CAS number of the registered substance under REACH. From these, 1917 have at least one consumer or commercial use in the US. We have at our disposal the accompanying information, such as the tonnages for the identified US uses.

Regarding chemical identity information, CDR mainly relies on CAS number apart from the 3% of chemicals for which confidentiality has been claimed for the chemical identity. In such cases (chemical identifying number is ‘A’), CDR uses an internal Accession Number that cannot be used for our screening. The CAS number will be either matched as such or through its corresponding structure using third party CAS-structure relationships. Care needs to be taken for importers who do not have a chemical name; in such cases the supplier needs to report the chemical identity of the chemical (not clear how such “joint” submission looks in the data model yet). Similar considerations apply in the case of manufacturers who do not have full knowledge of the reactants they are using in their process. CDR also contains a chemical name but it does not seem to be suitable for conversion into a chemical structure and it will not be used.

From the CDR data, we propose to check if there are any industrial, commercial or consumer uses in US to get some more information on how widespread can a use be. US EPA is using the CDR data for screening data, so it will be very worthwhile to discuss with them in the first opportunity how the CDR data were used in their algorithms.