Support to the Possible Introduction of Additional Information Requirements on Uses and Exposure in REACH

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Support to the Possible Introduction of Additional Information Requirements on Uses and Exposure in REACH

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Abbreviations

AC Article Category
AFA Application for Authorisation
ARN Assessment of regulatory needs
BREF Best available techniques REference documents
CAS Chemical Abstracts Service
CLH Harmonised Classification and Labelling
CMR Carcinogenic, Mutagenic, Reprotoxic substance
CoRAP Community Rolling Action Plan
CoU Conditions of Use
CSA Chemical Safety Assessment
CSR Chemical Safety Report
DU Downstream user
DU CSR Downstream User Chemical Safety Report
ECHA European Chemicals Agency
ERC Environmental Release Category
ES Exposure Scenario
GRA Generic Risk management Approach
IUCLID software to manage and exchange data on hazard properties of chemical substances
LCS Life Cycle Stage
MS Member State
OEL Occupational Exposure Limit
OSH Occupational Safety and Health
PBT Persistent, Bioaccumulative and Toxic substance
PC Product Category
PCN Poison Centre Notification
PROC Process Category
RAC Risk Assessment Committee
REEG REACH Exposure Expert Group
RiME+ Risk Management and Evaluation Platform
RMM Risk Management Measure
RMROA Regulatory Risk Management Options Analysis
SCEDs Specific Consumer Exposure Determinants
SCIP Substances of Concern in Products
SDS Safety Data Sheet
SEA Socio-Economic Analysis
SEAC Socio-Economic Analysis Committee
SPERCs specific Environmental Release Categories
SPIN Substances In Preparations in Nordic Countries
SU Sector of Use
SVHC Substance of Very High Concern
SWEDS Specific Workers Exposure Determinants
TCC Technical Completeness Check
TF Technical Function
vPvB very Persistent, very Bioaccumulative substance
1 Introduction

1.1 Background

Information on uses and exposures is one of the main building blocks of the approach under REACH. Use and exposure data are used for many of the processes under REACH, including registrant’s development of exposure scenarios including recommendations on operational conditions and risk management measures for his downstream users and the authorities’ Assessment of Regulatory Needs (ARN), restrictions, and monitoring of regulatory impact of REACH interventions (and the chemicals legislation at large).

This report analyses the shortcomings in the currently available use and exposure data generated through REACH registration and assesses the impacts of potential ways to improve the situation by revising REACH registration requirements and the associated downstream user (DU) obligations.

1.2 Objectives of the study

The objectives of the study are to:

- analyse the current situation including the shortcomings in the currently available use and exposure data;
- define a range of policy options for the revision of the current requirements; and
- assess the impacts of these policy options.

1.3 Structure of the document

This document is organised as follows:

- Section 2 summarises the key features of the methodology;
- Sections 3 and 4 provide the assessment of information needs and gaps;
- Sections 5 and 6 present the policy options; and
- Section 7 provides the Impact Assessment.

The detailed analysis of information needs is presented in Annex 1 and Annex 2. The long list of policy options is included as Annex 3.
3 Assessment of Information Needs and Gaps

In this section the authorities’ needs for information, its availability and potential gaps, and the consequences of missing information for the regulatory process is described. More details specifically on the information availability is provided in Annex 2. The section is structured according to the main categories of information that were identified as relevant. At the end of each section detailed improvement objectives are provided that link the assessment of information needs and gaps to the proposed policy options in Section 5.

3.1 Information on the Use Pattern

Information on the use pattern supports the general understanding of how, by whom, in which products and for what purpose a substance is used. This allows the identification of potential risks during use and service life and if and how these could be adequately controlled. The information category ‘use pattern’ includes information on:

- relevant life cycle stages
- products (mixtures and articles) in which a substance is used and the sectors of use
- uses that are covered by existing legislation as well as uses that could not be addressed by some of the REACH regulatory instruments (e.g. intermediates under the authorisation process),
- technical function of a substance and whether it is intended to be transformed
- in specific cases, information on an indicative number of workers exposed and a range of how many industrial sites use a substance
- range of how many consumers are exposed.

3.1.1 Information Needs for the Regulatory Processes

Information on the use pattern is needed for all regulatory processes. The assessment of regulatory needs, the monitoring of regulatory impacts and the generic restrictions under art. 68(2) can generally be conducted with information at the level of granularity implemented through the currently applied use descriptor system provided in ECHA’s guidance on use descriptors (ECHA 2016). Specific restriction proposals under art. 68(1) need (much) more granular information.

Assessment of regulatory needs (ARN)

In the ARN, the authorities (ECHA and the Commission) identify if a hazardous substance and/or any of its uses may cause exposures that might not be sufficiently controlled. For substances identified as candidates for regulation, they propose which regulatory instrument is most appropriate to address the identified potential risks (from specific uses). Prioritisation based on use and exposure proxies is a crucial step in the overall process, as a large number of substances are identified as requiring regulatory action and those with the highest risks should be addressed first.

Widespread use is the core indicator of a significant exposure potential. A use is assumed widespread if consumer or professional uses, or a service life, exist. Therefore, the life cycle stages (LCSs) are the basis for the ARN. Information on the products a substance is used in, the technical function (TF) it fulfils and if it is intended to transform increases the understanding of the uses and allows a refined estimation of the exposure potentials.

To identify an appropriate regulatory instrument, a holistic view on the use is necessary, including on the products the substances are used in. This information also indicates if uses are already covered by
existing (product-specific) legislation. Knowledge of intermediate uses is relevant, because it indicates a lower regulatory priority, and that authorisation cannot be used as regulatory instrument. If substances are only applied in industrial uses, additional and more specific information may be needed on the number of sites and the number of exposed workers in order to clarify the scale of potential risk. If substances are applied in consumer uses, the approximate number of potentially exposed consumers would be needed to clarify the scale of risk.

Some members of the RiME+ specified that also the used descriptor ‘Process Category’ PROC is considered important for the assessment of regulatory needs, as it indicates the exposure potential for workers.

The ARN does not involve any detailed risk assessments but relies on clarification of the hazard properties together with exposure proxies and indicative information that may be further refined in the potentially selected subsequent steps.

Consequently, the better the use pattern information is, the more precisely can regulatory candidates be identified and prioritised (low exposure or high exposure potentials, low or high capacity to manage risks in the market) and an appropriate regulatory instrument be selected.

**Restrictions**

A substance’s use pattern is a good starting point for scoping restrictions. Restrictions according to REACH Art. 68(2) (generic) are currently limited to the presence of substances in consumer products. Under the future Generic Risk management Approach (GRA), this may be further extended to products for professional uses. In general, based on GRA, the Commission would restrict all uses of substances on their own, in mixtures and in some articles. Derogations from GRA restrictions might be granted for some uses. Information on product categories (PCs) and article categories (ACs) may be sufficient to support a potential limitation of the scope of such restrictions.

Specific restrictions according to REACH Art. 68(1) generally need more granular information on the uses than currently defined by use descriptors for product and article categories to demonstrate that specific risks are not adequately controlled and to identify socio-economic impacts on the market sectors that could be affected.

Restrictions concerning Occupational Safety and Health (OSH) may need to be based on information on the numerical range of sites and exposed workers, while restrictions of consumer use could be justified on information on the exposed population³.

Consequently, whether the use pattern information at the current granularity is sufficient for specific restrictions cannot be stated at a general level; however, it does serve the purpose of scoping restriction proposals.

Restrictions initiated under REACH Art. 69(2) concern the occurrence of Annex XIV substances in articles and can be started only after ECHA has identified a need to address risks. The process follows the same procedure as under Art. 68(1) but focuses on risks from the service life and waste stage. Therefore, information is needed on those specific articles in which the Annex XIV substances are included. The registration information structured according to ACs is not sufficiently granular and up-to-date for specific risk assessments.

³ Monitoring data in the general population may be useful as well as assumptions on the likelihood of an exposure over time to justify a regulatory measure based on precautionary arguments.
Monitoring impacts of regulatory measures

Monitoring of regulatory impacts may be based on time trend information on the use pattern, i.e. in which types of products and for what type of users are substances applied and in which amounts. This is the case if a measure addresses the use in products either directly or indirectly, e.g. via a harmonised classification and labelling (CLH). If a substance is banned in a specific PC, this should show in the removal of that PC from the registration dossier as ‘identified use’ when the restriction enters into force. If use pattern data is only available from the time where a measure enters into force, it is uncertain if only the regulatory measure induced a change, or if other factors contributed to or even triggered it before the regulation entered into force. For example, if already before the decision to restrict a substance a cheaper or technically more suitable alternative is introduced to the market, the impact of a restriction cannot be clearly distinguished from a potentially already ongoing market trend to substitute. Therefore, time trends need be long-term rather than short term/on demand.

3.1.2 Availability and Quality of Information on the Use Pattern

Registration dossiers

Information on the use pattern is part of the technical dossier and many information types are subject to the TCC. Hence, basic data on the use pattern is always available.

Several shortcomings in the completeness, correctness, consistency, and unambiguity of the use pattern information hamper the implementation of specifically the ARN. The following table lists the identified main deficits per information type.

<table>
<thead>
<tr>
<th>Information type</th>
<th>Availability in registration dossier and observed shortcomings</th>
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<tr>
<td>Relevant life cycle stages</td>
<td>Inconsistent within and between registrations</td>
</tr>
<tr>
<td>Name of use</td>
<td>Sometimes no added value for understanding of the use provided</td>
</tr>
</tbody>
</table>
| Information on relevant product types (PCs/ACs of R12 guidance) | Information inconsistent, overreporting and underreporting of uses  
PCs for industrial and professional uses not subject to TCC and therefore frequently not provided  
No clear relation between TFs and PCs/ACs --> hampers understanding the use and resulting exposures  
List of PCs is not fit for purpose, e.g. includes very broad categories, some PCs are overlapping etc. |
| Affected sectors (SUs according to R12 guidance)      | Information on SU is voluntary --> not always provided  
SU partly very broad, sometimes relation to sector organisation missing (no reflection of formulator industry)  
Can usually be (better) identified from PCs/ACs but sometimes not                                                                  |
| Uses covered by existing legislation (that ensures control of risks) | Can partly be deduced from PCs/ACs but frequently not clear                                                                       |
| Uses not covered by (some) regulatory instruments      | Can partly be deduced from PCs/ACs but frequently not clear                                                                       |
| Technical function (TFs of R12 guidance)              | Information was not provided in dossiers with last update before 2016  
Partly unclear what the actual function is and/or if the TF has been correctly assigned                                           |
| Intended transformation due to the technical function | May be obtained from the TF but generally unknown; leads to significant uncertainty as to whether the substance or a reaction product is present in articles (including cured mixtures) |

4 The update of the registration dossier is required according to REACH Art. 22
### Table 3-1: Shortcomings of use pattern information

<table>
<thead>
<tr>
<th>Information type</th>
<th>Availability in registration dossier and observed shortcomings</th>
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<tr>
<td>Type of Process and emission/exposure potential (PROCs, environmental release</td>
<td>Information is typically provided in the registration dossier but the data are sometimes inconsistent and it is unclear what</td>
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<tr>
<td>categories (ERCs) of R12 guidance</td>
<td>was intended by the registrants.</td>
</tr>
<tr>
<td>Number of industrial sites applying a substance</td>
<td>Not currently available from REACH registration data</td>
</tr>
<tr>
<td>Number of exposed workers</td>
<td>Not currently available from REACH registration data</td>
</tr>
<tr>
<td>Number of exposed consumers</td>
<td>Not currently available from REACH registration data</td>
</tr>
</tbody>
</table>

**Information availability in other sources**

In addition to the REACH registration data, information on the ACs in which a substance is used is available for SVHCs on the candidate list from AfAs, notifications of substances in articles according to REACH Art. 7(2) and the Substances of Concern in Products Database (SCIP)⁵. This data may in particular support restriction proposals under REACH Art. 69(2) but is not relevant for non-candidate list substances.

The use pattern information may be verified and complemented using additional information sources, such as the Substances In Preparations in Nordic Countries (SPIN) database⁶ (existence of life cycle stages and PCs, partly also ACs), positive lists under e.g. biocides or cosmetics legislation (legal coverage), or DU CSR notifications (Art. 38). The Poison Centre Notification (PCN) database contains additional and valuable information on PCs⁷, specifically for drafting restriction proposals, but would require a legal change to make the information accessible for purposes other than the use by poison centres. Furthermore, data is limited to mixtures that are classified regarding human health and some physical hazards.

Generally, the ACs provided in the registration dossier are more difficult to verify than the product categories. It may be possible to verify the use of substances at the material level, e.g. from sector databases, such as the use of substances in plastics⁸ or lists of additives in paper production, but at the level of article categories, there is much less information available in other (external) information sources to verify if a substance is used in an AC or not.

For restriction proposals and the monitoring of regulatory impacts, information could be further complemented from literature, market surveys, MS product surveys, from websites of companies or sector associations, as well as from formal or informal consultations with the industry and other stakeholders. Some time-trend data may be available from e.g. the SPIN database but there are no requirements on regular updates. For the ARN, these options may be of limited use due to the partly high efforts needed to obtain and verify the information.

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⁵ [https://echa.europa.eu/de/scip](https://echa.europa.eu/de/scip)


⁷ The PCN is based on the European product categorisation system (EuPCS) v.3.0, which is more detailed than the PCs under REACH. [https://poisoncentres.echa.europa.eu/documents/1789887/7706312/eupcs_de.pdf/45ff01d-ab6f-beb1-acdd-41916b1a1d50?t=1635326536590](https://poisoncentres.echa.europa.eu/documents/1789887/7706312/eupcs_de.pdf/45ff01d-ab6f-beb1-acdd-41916b1a1d50?t=1635326536590)

⁸ E.g. Wiesinger et al. 2021
3.1.3 Causes of Information Gaps and Shortcomings

**Technical issues**

Among the technical issues that result in information gaps and a lack of reliable information are:

- Some information is not requested by means of specific IUCLID fields or some IUCLID fields are not subject to the TCC, including the intended transformation of substances, and the PCs for industrial and professional uses.
- Information on life cycle stages and PCs/ACs are inconsistent within registration dossiers (e.g. service life exists but no ACs provided).
- Because exposure scenarios (ESs) frequently cover more than one function and several PCs/ACs, it cannot be clearly understood which particular function a substance fulfils in which of the products.
- The use descriptors for TFs are partly difficult to understand and the PCs are not fully fit for purpose, e.g. the PC ‘adhesives and sealants’ covers various products applied using a wide range of techniques (resulting in different emission and exposure patterns) and the PC 15 ‘non-metal surface cleaning’ overlaps with several other PCs, such as PC9a ‘Coatings and inks’, which makes it unclear, what is actually covered by which PC.
- The description of PROCs and ERCs appears to be partly unclear to the registrants.

**Registration requirements**

REACH requires registrants to update their registration dossiers if they identify or advise against a new use (Art. 22(1)d). Registrants must also update their dossiers to include any relevant information compiled in an AfA as well as to include any authorisation or restriction decision that is relevant for their substances (Art. 22(2)). However, many registration dossiers contain outdated or restricted uses, i.e. changes in use pattern over time are not reflected. This means that registrants do not always keep their registration dossiers up to date; there are limited incentives to update their dossier for a substance that they do not use anymore because it has been placed on Annex XIV or restricted in Annex XVII. There is no requirement to update registration dossiers at regular intervals.

**Knowledge in the supply chain**

Most registrants (i.e. manufacturers or importers of the substance) have limited information on the (end-) use of their substance. The further up the supply chain and the more specific the use of a substance is, the more likely the registrants know of the uses. For commodity substances the registrants’ specific information on the use pattern is even more limited than for specialty chemicals.

To overcome the registrants’ lack of knowledge on the Conditions of Use (CoU) of the DUs, the so-called sector use maps have been developed by downstream use sector organisations. Sector organisations clustered the various uses into groups, indicating the PCs applied, the PROCs implemented and the applicable ERCs as well as, if existing, standardised and more specific exposure information from Specific Workers Exposure Determinants (SWEDs), Specific Consumer Exposure Determinants (SCEDs) and Specific Environmental Release Categories (SPERCs). Registrants can select the uses they want to identify from the use maps and use the related standardised exposure information for their CSA. The aim of the use maps is to

a) Support DUs in communicating their uses and in particular the CoU to the registrants in a harmonised and structured way and
b) Bundle and thus simplify the chemical safety assessment (CSA) in the registration process.
To support such standardised communication that fits to the registrants’ CSRs, PCs and ACs with comparable CoU were merged. The sector use maps invite registrants to identify all provided uses for which they can demonstrate safe use, so they cover all potentially relevant markets. To what extent the uses in the registration dossiers (still) exist can only be verified by the authorities if the registration information is compared with other information sources.

Downstream users are aware of their own use pattern and potentially also the uses further downstream. Formulators know for what end-uses they produce a product and the sector they supply. Formulators’ knowledge about the articles in which their mixtures end up may be ‘good’ but may also be ‘very limited’, depending on the specificity of the substance/mixture, the complexity of the supply chain and the diversity of uses.

In the context of the REACH Review 2018, an action programme was developed (REACH Review Action 3) to improve supply chain communication, amongst others by further developing communication tools and digitalising communication (electronic safety data sheets (SDSs)). If resumed, these activities could improve the information flow on chemicals downstream and (to a lesser extent) also upstream and may hence also improve the availability of use and exposure information.

As information on the use pattern indicates market potentials, it is considered confidential, especially by the formulators. Therefore, upstream communication on use pattern information is unlikely to be successful, specifically if highly granular. Furthermore, the trigger for upstream communication according to REACH Art. 34 (receiving inappropriate RMM information) is subject to interpretation and hardly enforced so that most DUs do not see a need to communicate upstream.

While some deficits in IUCLID and the guidance documents contribute to information gaps and insufficient information quality, the registrants’ lack of knowledge about the downstream uses of their substances and the non-functioning upstream communication is considered the root cause, why the use pattern information is not reliable and partly inconsistent and incomplete.

### 3.1.4 Possible Consequences of Insufficient Information

If information on the use pattern is inconsistent, ambiguous, incomplete, or incorrect, all regulatory processes may be negatively affected. If existing uses are not sufficiently well identified in the registration dossier, potential risks may be overlooked and the aim of REACH to ensure a high level of protection for human health and the environment may be failed because substances (or their critical uses) are not subjected to a regulatory procedure at all.

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9 An example is the formulation of mixtures in bulk processes: There is generally no difference in the process of formulating a product in the PC 1 or the PC 9a. The risks are rather determined by the PROC and the ERC and the specification of a PC is only needed for the (later) downstream communication to enable the recipient to check if he is covered by the assessment. However, for specific products, the formulating conditions may differ, e.g. to avoid reactive components to react during production. Such cases may be separately addressed in the use maps if these differences in CoU influence the emission and exposure, or may be included in the same way as other the formulation processes.

10 As the lack of upstream communication is not only a problem of missing standards and digitalisation, the effects of the action there are only minor impacts expected on the availability of use and exposure information in registration dossiers.

11 In developing AfAs, DUs communicate detailed information on the use pattern and CuOs among each other and/or to their suppliers. This shows that in principle the information is available and can be presented if this is necessary to prevent the phase-out of a substance.
This could be the case if

- **LCSs** are not identified as relevant (i.e. consumer uses or article service life missing)
- **PCs or ACs** with high release potential are not identified
- The **transformation products** of a substance are more hazardous than the parent compound and result in higher risks during life cycle stages following the transformation.

It was reported by a RiME+ member that they researched the use of substances in consumer products in substance evaluations. The SPIN database and other information sources gave clear indications of the substance being included in consumer products, while no or ‘negligible’ consumer use was identified in the registration dossiers. For these substances, the use has been identified in the course of the evaluation process, but there may be other cases, where the use of substances in consumer products remains undiscovered and risks could occur.

In the process of restricting carcinogenic, mutagenic and reprotoxic substances (CMRs) in textiles (GRA restriction under art. 68(2)), the initial long list of substances based on registered uses in textile articles and SVHC notifications was considerably shortened after reviewing the up-to-date information on the use of these substances and stakeholder consultations. This shows that the iterative process of the restriction and consultations with stakeholders may correct wrong assumptions about an appropriate regulatory scope, especially if the restriction concerns a well organised sector and a specific use. However, consultations may not sufficiently support the identification of uses that are not reported (in products for consumer (or professional) use).

If non-existing uses are identified (overreporting), the risks might be overestimated, and resources be wasted to design (superfluous) regulatory measures that result in no/low risk reduction and unnecessary costs for the stakeholders. In addition, this may delay the risk management of substances, requiring risk management more urgently (failing to ensure protection level early). This could be the case if:

- **LCSs** are indicated as relevant, but do not exist in practice (e.g. due to a restriction)
- **PCs or ACs** are part of identified uses, which in reality do not exist

Examples, where an overreporting of uses triggered screening and evaluation work which did not result in a regulatory risk management process and can hence be considered as unnecessary use of resources include:

- the registration dossier of 3,3′-dimethylbiphenyl-4,4′-diyl diisocyanate (CAS 91-97-4) initially indicated consumer uses, and for this reason it was included in the Community Rolling Action Plan (CoRAP) for substance evaluation. During the process the registrant removed the consumer uses from the registration. Meanwhile, more information on hazards justified by wide dispersive uses was requested.
- A Regulatory Management Options Analysis (RMOA) was started on persulfates, where consumer uses in swimming pools and metal surface treatment were initially registered. These uses were removed when registrants were required to improve the respective assessment CSR.
- Triclocarban (CAS 101-20-2) was shortlisted for evaluation in the CoRAP based on a screening analysis but registrants announced cease of manufacture when the evaluation started.

It should, however, be recognised that it is not known to what extent these uses had already ceased before more information was required (i.e. the registrations did not reflect the actual uses) or whether the registrants decided not to support these uses as a result of the request for more information.
Insufficient use and exposure information could also cause a wrong decision on the regulatory instrument, which could result in failure to address all risks, double regulation and/or inconsistent legislation, or creation of disproportionate regulatory pressure on the market. Such consequences might result from wrong registration information on life cycle stages, products, or sectors using a substance.

Substances may be included in the candidate list, even though no uses exist that could be subject to authorisation. This could mean that unnecessary resources are spent on SHVC identification and an assessment of whether the substance should be subject to authorisation. It is recognised that candidate listing is/was the only way to formally conclude on the ED and PBT/vPvB status of such substances and some substances have been included in the Candidate for this reason even where the dossier submitter did not intend to include the substance in Annex XIV. It is also recognised that designation as SVHC may also have an impact on how the substance is treated by some downstream legislation, e.g. legislation on water pollution.

Overreporting of uses may result in starting a restriction proposal which later may have to be withdrawn as the uses considered critical do not exist.

### 3.1.5 Targets for Improving the Information on the Use Pattern

An overall improvement objective is that authorities should have access to up-to-date information on the use pattern so they can base their assessments and decisions on actual information rather than obsolete use patterns. The following list of improvement objectives focusses on the assessment of regulatory needs and priority setting processes, as well as the monitoring of policy impacts. Where an improvement objective is specific regarding a particular regulatory process, this is indicated in the wording of the improvement target.

#### Information on life cycle

- Ensure that ECHA, Commission and the MSs obtain reliable information on the user groups of a substance (industrial, professional and consumers) and the existence of an article service life to identify exposure potentials and get an understanding of the appropriate regulatory instrument, including GRA restrictions, to address risks.
- Improve the authorities’ understanding of the lifecycle of a substance by ensuring that technical functions are clearly linked to PCs and it is reported which PCs enter a service life and in which ACs.
- Ensure the information on occurrence in articles is reliable and sufficiently granular, i.e. indicating if articles are for professional or consumer use and what potential exposures could arise from service life and waste treatment, amongst others to prioritise the need for (generic) restrictions.

#### Product categories

- Ensure that all relevant PCs of a substance are identified in the registration dossier and up-to-date, so the authorities get a complete picture of the relevant mixtures.

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12 There may be other reasons for candidate listing than authorisation, e.g. to officially identify a substance as a PBT, vPvB or an endocrine disruptor.
• Ensure that the use descriptors of PCs are relevant, understandable and give an indication of whether legislation exists that addresses the risks to reduce uncertainties about their correct use by registrants and better enable deriving exposure potentials.
• Ensure that the PC system is consistent and flexible enough (potentially via a hierarchical organisation addressing needs for different granularities of PC information) to address all information needs of regulatory processes, as well as their function in supply chain communication.
• Ensure that the authorities have access to specific information on a substance’s uses in mixtures to scope and target restriction proposals, to compensate the too low granularity of product information in the registration dossiers and allow specific restrictions to be developed.

**Article Categories**

• Ensure that all relevant ACs are provided in registration dossiers to enable prioritisation for generic restriction proposals.
• Ensure that authorities can estimate exposure potentials from articles from ‘high’ to ‘low’ in order to prioritise regulatory action.
• Ensure that ACs are defined so that regulatory coverage can be identified in the assessment of regulatory need.
• Ensure that the authorities have access to (stakeholders having) information on specific articles a substance is included in (higher granularity than ACs) to scope and target restriction proposals, make risk assessments and identify socio-economic impacts.

**Sector of use**

• Ensure that the authorities get access to sufficiently detailed information on the (type of) sector a substance is used in so they can get an impression of the related markets and identify the relevant stakeholders.

**Technical function**

• Increase consistency and correctness of the TFs assigned to substances by improving the registrants’ understanding of (individual) TFs to make this information more reliable for use-based grouping and identifying the interchangeability of substances (prevent regrettable substitution, avoid inconsistent regulation and support the identification of alternatives when drafting restriction proposals).
• Ensure that the granularity and wording the TF use descriptors is aligned with the way how registrants structure their product portfolio and name their products; avoid doubling, superfluous or ambiguous TFs / terms. This would improve the reliability of the registration information as such and improve the understanding of a use (for ARN and restrictions).
• Ensure a clear and consistent relation between a substance’s TF and the PCs and ACs in which it is used to improve the understanding of the uses.

**Intended transformation**

• Ensure substances that are intended to be transformed during use are flagged to allow authorities checking the plausibility of LCSs and consider transformation products in risk assessments.
**PROCs / ERCs**

- Ensure a common understanding on the use, emission and exposure conditions of PROCs and ERCs, so the registrants use them as intended in their CSA and they can be used as a proxy for the exposure potential by the authorities.

**Industrial sites and exposed workers, exposed consumers**

- Enable the authorities to collect information on industrial sites using a substance and workers being exposed if necessary to identify the need for risk management and/or targeting specific measures, and to monitor the impacts of measures.
- Enable access to information on exposed consumers to support the identification of a regulatory need and to monitor the impacts of measures.

### 3.2 Tonnage information

Information on tonnages is mainly needed as a proxy of the overall exposure potential. Information on tonnages per use is needed to weigh different uses against each other, to thereby determine their relevance, and to monitor the impacts of regulation in terms of changes in market volumes per use/PC/AC on the markets. Tonnage information facilitates deducting fractions of substances for which exposure is considered sufficiently controlled. Tonnage information is also needed to develop restriction proposals. Here, the granularity of information on input data for risk assessments and SEAs depends on various factors, including the type of restriction (specific/generic), the type of substance etc.

The information needs identified in the category 'tonnage information' include:

- Total consumption volume in the European Economic Area (registered tonnage (manufactured plus imported) minus tonnage immediately exported by the registrant)
- Tonnage per LCS
- Tonnage used as intermediate / covered by legislation
- Tonnage per group of uses and/or per product category (AC/PC)
- Tonnage per use at higher granularity as AC/PC.

#### 3.2.1 Information Needs for the Regulatory Processes

**Assessment of regulatory needs**

For the ARN, the authorities need information on the overall consumption volume (manufactured and imported minus exported tonnage) as an exposure proxy to rank overall action needs, and for the recommendation of SVHCs for inclusion in Annex XIV. The consumption volume indicates the extent of market impacts a regulatory measure could have.

Information on tonnages entering a particular LCS (consumer, professional, industrial use, and service life) and at a higher granularity entering a use and/or being included in PCs/ACs allows weighing the relevance of different applications of a substance (with the associated exposure potentials). Amounts of substances covered by legislation as indicated by a PC or AC could be deducted from the overall amount potentially requiring regulatory action. Information on tonnages also supports the identification of the most appropriate regulatory measure. The granularity of information on tonnages is closely related to the granularity of use reporting.
**Restrictions**

Drafting restriction proposals according to Art. 68(1) needs tonnage information as input to the environmental risk assessment as well as for the socio-economic analysis (SEA). Specific restriction proposals require the information at a higher granularity than the assessment of regulatory impacts and the ARN.

For generic restrictions and possibly the future GRA approach, consumption volumes are needed to prioritise substances for the restriction procedure as such, and tonnage information per PC/AC may support the decision making on which products should be included under the restriction scope.

**Monitoring impacts of regulatory measures**

The changes in overall consumption volumes and tonnages entering specific LCSs and/or uses are key indicators to determine if a regulation has impacts the uses in the market and, indirectly, if it reduces exposures as intended.

### 3.2.2 Availability and Quality of Tonnage Information

**Registration dossiers**

Information on the production and import tonnage of substances such and in mixtures) is subject to the TCC in IUCLID. The registrants may report the amounts used as an intermediate under strictly controlled conditions, the exported amounts and the amounts used in their own uses on a voluntary basis. It is necessary to specify the tonnages entering a use for the assessment of environmental emissions and exposures in the CSR. Cumulative tonnages per LCS can be derived based on the CSRs and/or provided on a voluntary basis in IUCLID.

<table>
<thead>
<tr>
<th>Information type</th>
<th>Availability in registration dossiers and observed shortcomings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total consumption volume in the European Economic Area</td>
<td>Information not up-to-date</td>
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<tr>
<td></td>
<td>Exported amounts not always provided</td>
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<tr>
<td></td>
<td>Amounts exported in mixtures and articles as well imported in articles unknown to registrant</td>
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<tr>
<td></td>
<td>Inconsistencies with reported amounts per use</td>
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<tr>
<td>Tonnage per LCS</td>
<td>Information not up-to-date</td>
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<tr>
<td></td>
<td>Tonnage per LCS inconsistent with total amounts</td>
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<tr>
<td></td>
<td>Tonnage ending up in articles (service life) and end uses not always available (not subject to TCC); however, filled in automatically if Chesar is used for CSA</td>
</tr>
<tr>
<td></td>
<td>Cumulated information from Chesar / CSR is not considered reliable</td>
</tr>
<tr>
<td>Tonnage used as intermediate,</td>
<td>Reporting of intermediate uses voluntary (but related to benefits of lower hazard information requirements)</td>
</tr>
<tr>
<td>tonnage covered by other legislation</td>
<td>Tonnages not reported according to ACs/PCs that indicate regulatory coverage</td>
</tr>
<tr>
<td>Tonnage per use</td>
<td>Information in ESs (environmental assessment) of the CSRs not considered reliable</td>
</tr>
<tr>
<td>Tonnage per product category (AC/PC)</td>
<td>Information missing unless ES covers only one PC/AC (then available from environmental assessment)</td>
</tr>
<tr>
<td></td>
<td>No information on tonnages in imported articles available</td>
</tr>
<tr>
<td>Tonnage per use at higher granularity as AC/PC</td>
<td>No information on amounts used per product at higher granularity than PC/AC available</td>
</tr>
</tbody>
</table>
**Information in other sources**

Information on the consumption volume and volumes entering specific uses covered by (product-specific) legislation is not easily available and accessible to the authorities from databases or similar sources. Indeed, it may not be available at all, due to a lack of substance specific reporting systems. While EU production and trade statistics may contain information on a few specific commodity chemicals, this information is missing for lower volume and specialty substances. Furthermore, matching of the use information reported in e.g. the Production Statistics with the use descriptions in registration dossiers is hardly possible.

**3.2.3 Causes of Information Gaps and Shortcomings**

**Technical issues**

- There are no plausibility checks highlighting inconsistencies to registrants
- Tonnages used to estimate emissions and exposures in the CSR do not reflect market reality but are frequently back-calculated so as to ensure safe use; therefore consistency between registration volume and summed up amounts from CSRs is not possible in general

**Information requirements**

At present, not all information that registrants are likely to know or at least able to provide in ranges based on market knowledge and customer profiles must be provided and is subject to the TCC, such as the own exported amounts or a breakdown of tonnages according to ‘main groups of uses’. In addition, a requirement to regularly or on demand update tonnage information does not exist, except if tonnage bands are exceeded (COM 2020).

**Knowledge in the supply chain**

The registrants’ knowledge of the tonnage breakdown per use is limited, as they do not oversee the entire supply chain. However, based on their market knowledge, sales statistics and main customers, they should have a general understanding of the destination of their substances in terms of ‘fractions of their total production volume’. Their knowledge is most limited regarding the amounts entering service life (and into which specific ACs).

The authorities do not rely on the tonnage information derived from the environmental exposure assessments of the CSR. The lack of reliability is due to the aim of the CSR being the demonstration of safe use via a tiered safety assessment starting with default assumptions on the CoU (including tonnage). The total tonnage per use as well as the use tonnage per installation are important exposure drivers and hence their values are likely to be iterated in the CSR in a way to demonstrate safe use. It is unclear if the resulting amounts reflect the market shares that in reality are included into the specified PCs/ACs or uses. In addition to that, the ESs frequently cover more than on PC/AC and therefore, the tonnage information in the CSRs is not available at a granularity needed for specific restriction proposals.

The DUs have information on the amounts of substances that they include into their products (mixtures) and, if they use substances in mixtures, they know the tonnages as ranges. Similarly, article producers know the amounts included into their products as ranges. However, information on the used tonnages per use and/or per PC/AC is considered confidential, as it indicates a market potential in a particular application. It is therefore not communicated upstream.
3.2.4 Possible Consequences of Insufficient Information

Assessment of regulatory needs

Insufficient or outdated information on a substance’s consumption tonnage may result either in an underestimation of the regulatory need and in a failure to ensure a high level of protection, or in an overestimation of a substance’s relevance resulting in a potential waste of resources for (unnecessary) regulatory assessments as well as a delay in risk management of other, more relevant substances due to resources being consumed. As the own production and export volumes are well known to the registrants, it is considered likely that this particular information can be provided in sufficient quality.

Outdated or wrong information on the tonnage breakdown per use may result in subtracting too high or too low amounts that enter intermediate uses or are covered by legislation, thus wrongly reducing or increasing the priority of a regulatory need.

Wrong or outdated information on the tonnage breakdown per use could also mislead the authorities’ selection of the most appropriate regulatory instrument. This selection considers the tonnage breakdown with a view to (most efficiently) addressing the majority of potential risks via one measure as well as with a view to limiting unwanted effects (in the market), such as regrettable substitution, a high level of incompliance and/or an ineffective measure causing much implementation work (i.e. high number of authorisation applications or efforts to enforce restrictions that are not relevant).

Reliable information on tonnages per lifecycle could improve the risk management processes, for example:

- Exclusive use (in articles) in industrial settings indicates that risks may already be addressed. This could enable deciding that the risk management is sufficient or needs to be further enhanced, e.g. by a CLH or the definition of Occupational Exposure Limits (OELs).
- Major shares of the registration tonnage entering consumer and professional uses could exclude authorisation as a regulatory measure, by a preference to regulate via (an extended) Article 68(2).
- The existence of an article service life may indicate (generic) restrictions as the most appropriate regulatory measure.

Reliable information on the tonnages per TF, PC or ACs could facilitate:

- Priority setting when intermediate uses (TF) can be deducted from the consumption volume.
- Priority setting and selecting a regulatory measure when amounts can be deducted that are already covered by legislation (PC).
- Excluding the use of the authorisation as a regulatory instrument, if it is known that large volumes of a substance enter the EU via the import of articles or if intermediates cause risks (TF/AC).

Depending on what information is wrong, missing or outdated, the decision could result in starting a regulatory process unnecessarily or concluding a regulatory process that ends up in double regulation, inconsistent legislation, failure to address (all) relevant risks, waste of resources due to the covering irrelevant uses or failure to exert substitution pressure in the right markets.

Restrictions

Generic restrictions (REACH Art. 68(2)) of substances in consumer articles may be initiated based on information on such uses. In the future, this may be extended under the GRA to products used by
professionals. If the tonnage break-down wrongly indicates uses in products for consumer or professional use, a regulatory need could be underestimated and a regulation opportunity be missed, or an ineffective (and therefore inefficient) restriction proposal may be started if uses do not exist.

The lack of up-to-date and specific tonnages per use for drafting specific restriction proposals according to REACH Art. 68(1) may result in inappropriate restriction scopes.

A lack of tonnage information per use makes it difficult to calculate releases, thus aggravating the prioritisation of uses that should be covered by a restriction. This means that there is some potential for restriction proposals to be unable to demonstrate that risks are not controlled due to a lack of certainty about the substance tonnages entering that use and the related inability to demonstrate an unacceptable risk. This would mainly concern environmental risks but could also be relevant for risks to consumers.

Wrong or outdated tonnage breakdowns per use would hamper a realistic assessment of socio-economic impacts, as no clear picture exists about the extent to which current production processes or products would have to be changed. The SEAC has developed methods and approaches to deal with such uncertainties.\textsuperscript{13}

\textit{Monitoring impacts of regulatory measures}

Monitoring the impact of regulatory measures needs time trend information on the overall consumption and, depending on the type of regulatory instrument, also on tonnages entering specific uses. If tonnage information is not provided regularly, changes in the market cannot be assessed and an important indicator for measuring success is missing. The more detailed the tonnage information is, the better can the market reactions be understood and, in case it becomes evident that the regulatory goal cannot be reached, the regulatory action may be refined or modified. If this information is not available, ex post impact assessments either require specific additional data collection or incorporate uncertainties.

\textbf{3.2.5 Targets for Improving Tonnage Information}

\textit{Total consumption volume in the European Economic Area}

- Ensure authorities have up-to-date information on the annual consumption volume of substances, i.e. the tonnages produced, imported on their own and in mixtures and exported by the registrants.

\textit{Tonnage per LCS}

- Ensure up-to-date information on the tonnage breakdown per LCS (industrial use, professional use, consumer use) is available, so authorities can better identify the exposure relevance of a substance for different user groups and select regulatory measures accordingly.
- Make information on the total volume of a substance entering articles available, including an indication if a substance is present in the article in its original form or if it is transformed, to give the authorities an indication of the relevance of the service life.

\textsuperscript{13} Cf. for example Wirth et al (2021)
**Tonnage used as intermediate**

- Provide the authorities with up-to-date information on the tonnage used as an intermediate.

**Tonnage breakdown per use**

- Ensure registration dossiers include up-to-date and reliable information on the substance tonnage applied in (groups of) uses with similar exposure potentials for assessing the regulatory need.
- Ensure time trends on the use amounts per (specific) PCs/AC are available for policy success monitoring and scoping restriction proposals.
- Ensure the authorities have access to detailed information on the use amounts per PC and AC to target restrictions, demonstrate a need to control risks and make a SEA.

### 3.3 Information on the Conditions of Use (CoU)

The Conditions of Use (CoU) may support the understanding of the exposure resulting from the use of a substance. Information in the category ‘Condition of use’ includes:

- Exposure drivers related to products, such as physical state of mixtures, concentration in mixtures or articles, type of matrix binding of a substance
- Operating conditions of processes, such as frequency and duration of use, processing temperature, degree of process containment, occurrence of water contact
- Exposure drivers related to the service life, such as high temperatures during service life, abrasive conditions, outdoor use of articles, location of an article in a complex object
- Risk management measures (RMMs) during use and waste processing.

### 3.3.1 Information Needs for the Regulatory Processes

Information on the CoU may be used in the assessment of regulatory needs as supporting information but is mainly needed for drafting restriction proposals. Its need for policy success monitoring depends on the type of regulatory measure that should be evaluated.

**Assessment of regulatory needs**

Exposure proxies inherent to a product or use, such as the concentration of a substance in a product, the level of containment of a process or the existence of abrasive conditions during service life, may support the ARN by enabling a refinement of initially assumed exposure proxies of the use pattern. This use of information was stated as relevant by some MS competent authorities in their written comments and at the RiME+ discussions. For example, if service life is the reason to prioritise a substance for risk management, information on the matrix binding, migration rates and/or whether the substance is contained inside a complex object or is present on its surface could change the assumption on the exposure potential and thereby the regulatory priority and/or choice of regulatory instrument. Such information is particularly important for a future prioritisation of restrictions of uses in articles under REACH (and also for prioritising restrictions under Art. 68(2) as well as under Art. 68(1)).

Information on the CoU is not needed but could improve the ARN. It is not used for recommending SVHCs for the authorisation process.
Restrictions

Knowledge about the CoU is necessary to develop specific restriction proposals (Art. 68(1)) as input data to risk assessments (emission and exposure modelling) and the basis to define specific conditions of a restriction, e.g. regarding the RMMs. The information is also needed to develop scenarios for the SEA. Generic restriction proposals for mixtures do not rely on information on the CoU (as high exposure potential is assumed), whereas this might be very important for the prioritisation of restrictions of uses in articles.

Monitoring impacts of regulatory measures

If a regulatory measure should be monitored that aims to change the CoU (including the article service life), time trends on these conditions are needed to assess if the measure is successful.

3.3.2 Availability and Quality of Information on the Conditions of Use (CoU)

Registration dossiers

<table>
<thead>
<tr>
<th>Information type</th>
<th>Availability in registration dossiers and observed shortcomings</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoU driving exposure that are related to the products (physical state of mixtures, concentration in products, type of matrix binding, containment inside (complex) objects etc.)</td>
<td>Physical state and concentration in products are provided in CSRs (contributing scenarios) but are not obligatory in IUCLID and frequently not imported from Chesar (if used). Information on the type of matrix binding is not explicit in exposure assessment and no data field is available in Chesar/IUCLID. Mostly generic information is provided as derived from use descriptors and exposure assessment tools (PROCs, ERCs/SPERCs, ECETOC TRA and others).</td>
</tr>
<tr>
<td>Operating conditions driving exposure related to the use process, such as operating temperature, degree of process containment, occurrence of water contact</td>
<td>Information on relevant exposure determinants during use is provided in CSRs (contributing scenarios) but are not obligatory in IUCLID and frequently not imported from Chesar (if used). Mostly generic information is derived from use descriptors and exposure assessment tools (PROCs, ERCs/SPERCs, ECETOC TRA and others).</td>
</tr>
<tr>
<td>Exposure drivers related to the service life, such as high temperatures during service life, abrasive conditions, outdoor use of articles</td>
<td>Information on relevant exposure determinants during service life may be provided in CSRs (contributing scenarios on service lives) but are not obligatory in IUCLID and frequently not imported from Chesar (if used). Mostly generic information is derived from use descriptors and exposure assessment tools (ERCs/SPERCs, ECETOC TRA and others).</td>
</tr>
<tr>
<td>Operating conditions and RMMs during use and waste processing</td>
<td>Information on operating conditions and RMMs applied during use is provided in CSRs (contributing scenarios) but is not obligatory in IUCLID and frequently not imported from Chesar (if used). Mostly generic information is provided from use descriptors and exposure assessment tools (PROCs, ERCs/SPERCs, ECETOC TRA and others).</td>
</tr>
</tbody>
</table>

The above information may be provided in variable levels of completeness, with the use of Chesar decreasing the likelihood of missing information.

Information in other sources

Information on the CoU of industrial processes (but usually without reference to specific substances) is available in the literature, such as BREF documents, sector information or company websites.
inspection reports, or technical reports, such as the consexpo factsheets for consumer uses. Information on the conditions during service life may be ‘simple’ for many consumer articles but less known and obvious for articles that are part of complex objects or applied under extreme conditions, for example. In any case, this information is not easily accessible and would have to be researched case by case, e.g. to support a restriction proposal.

Of the REACH information sources, the Downstream User Chemical Safety Reports (DU CSRs) may include additional information on the CoU. However, as the DUs only notify the fact that they conduct a DU CSR but are not required to submit it to ECHA (or to the MS CAs), these would have to be specifically requested by the authorities to evaluate the CoU.

The SCIP database can be used as a starting point to derive information on the CoU, as the types of ACs frequently indicate what the CoU are like (common sense and general knowledge of articles and their use under normal and reasonably foreseeable conditions). However, information in this database is restricted to substances on the candidate list (and in some cases is of low quality).

AfAs contain information on CoU in several processes and might be an information source for substances applied in similar applications. As the AfAs are likely to be more specific than the ESs in registration dossiers, further and more granular information on the CoU could be derived.

Consultations may generate information on the specific CoU, too. However, all this information is scattered, may not be available or applicable to the substance under question, is cumbersome to access and normally not available for the ARN.

Information could be gathered directly from stakeholders via formal consultations but also informal information collection, e.g. Calls for Evidence or in discussions during dossier preparations. Similar to literature research, this type of information gathering is cumbersome and probably only realistic to support restriction proposals.

### 3.3.3 Causes of Information Gaps and Shortcomings

#### Technical issues

- Not all information that is provided in the CSR is available in IUCLID, i.e. in a structured data format. Some exposure drivers, such as the process containment or the existence of water contact during processing are determined via the selected PROCs or ERCs but others are not, such as the type of binding to a matrix. IUCLID fields to provide that information, including separately from that provided in the CSR, do not exist.
- The used descriptors of the PROCs and ERCs are not consistently and sufficiently differentiated according to main exposure drivers. For example, the general and rough differentiation for high or low release from articles is not sufficient to substantiate a risk assessment justifying a restriction.
- The registrants appear to not fully understand the meaning of the ERCs and PROCs, which shows in inconsistent use descriptions (i.e. within a registration dossier but also the same use being described differently in different registration dossiers for the same substance).

#### Registration requirements

There is no legal requirement defining the type and granularity of information on the CoU that must be provided in the CSR. Data import from Chesar can be suppressed and there are no data fields on
the CoU that are subject to the TCC. Minimum requirements for describing the CoU in ESs do not exist, yet.\footnote{The REACH Review Action 3 included a task for ECHA to develop minimum requirements to exposure scenarios to define what information must be provided by the registrants. However, the work on the minimum requirements has been put on hold by ECHA’s Management Board due to resource constraints.}

- Due to the purpose of the CSR, registrants describe the CoU as broadly or as narrowly as necessary to demonstrate safe use.
- DUs may need information on the CoU in ‘their language’ to understand if they are covered by an ES.
- The authorities have varying needs regarding the granularity of information on the CoU depending on the whether a planned restriction is generic or specific, if the substance is very hazardous and what type of use/PC/AC is targeted

**Knowledge in the supply chain**

The main reason for the lack of specific information on the CoU is that registrants do not have this information and therefore cannot specify it in the registration dossier.

The tools to bridge the registrants’ lack of knowledge, such as exposure estimation and modelling tools, potentially including default values on the CoU, sufficiently work to enable the CSA. However, due to their generic nature and uncertainties about if and how the CoU are implemented in the market (lack of upstream communication on the CoUs and about waste treatment due to a lack of the waste sector being actively involved under REACH), the authorities do not consider the CoU information as sufficiently reliable for regulatory risk management.

The DUs know the conditions of their own processes and potentially also those of their customers and/or the article service life. While they might not be aware of the exact concentration of a substance in their products due to safety data sheets (SDSs) only specifying concentration ranges, they know the physical state of their mixture, the way a substance is bound to a matrix (if this is relevant) and how they operate their processes. Article producers normally are aware of the type of (end-)products their articles are included into and can predict which type of exposure driving conditions could exist. In summary, knowledge on the CoU is available at the DUs but it is currently not provided upstream to the registrants for inclusion in the CSR and/or technical dossier.

**3.3.4 Possible Consequences of Insufficient Information**

**Assessment of regulatory needs**

The concentration of substances in products as well as the physical state of mixtures and the matrix binding of substances could be helpful to check if an expected exposure potential is significantly over- or underestimated. Hence, the availability of this information reduces the likelihood that regulatory candidates are overlooked or that an inappropriate regulatory instrument is selected for uses, which are not of high relevance. Likewise, information on relevant exposure drivers during industrial processing may support the identification of appropriate regulatory instruments, where substances are only/mainly applied in industrial uses. For the ARN, information on the CoU may be useful but generally plays a minor role for assessment and decision making. Therefore, the consequences of missing information are considered as minor.
Restrictions

For specific restrictions (Art. 68(1)), information on exposure drivers, operational conditions, and RMMs during uses and service life is needed to show if and which risks are currently not adequately controlled and therefore require addressing. It is needed to design process or product related conditions of a restriction. Furthermore, it is needed as input to the SEA.

If supportive evidence from CoU is missing, the authorities may not be able to demonstrate a risk and thereby to justify a restriction. Resources may be spent on the assessment without a clear conclusion and in the worst case, problematic uses might not be recognised and hence continue. This could happen if information on the concentration in and migration potential from products is under- or overestimated or if the CoU indicated in the registration dossier are not in place.

A restriction may target irrelevant products or processes and thereby either address only a minor share of the risk (level of protection is not ensured) and/or cover areas, where a restriction causes disproportionate market impacts compared to the benefits. Vice versa, if information on the CoU is available, it may be possible for the authorities to base their restriction proposal on this information as input to exposure models. For example, for the restriction proposal of N-methyl-2 pyrrolidone the Dutch authorities relied on the information from CSRs as input to the Tier 1 assessment (EasyTRA). Based on this, they identified that the risk characterisation ratio is exceeded in many settings, even though RMMs were assumed in place. The RAC accepted the argumentation of lack of adequate control of risk and the related scoping and definition of conditions of the restriction (ECHA 2014a).

As the restriction process is iterative and the authorities use additional information sources to develop their proposals, such as sector documents, scientific literature, exposure models or input from formal and informal consultations, the scopes and conditions of a specific restriction are developed considering this additional information. This means that the main consequence of missing information appears to be that authorities spend (additional) resources on information gathering, structuring, and evaluating.

Monitoring impacts of regulatory measures

Information on the CoU is only needed for policy impact monitoring if the respective regulatory action targets one or several of these conditions. For example, if the restriction conditions require the implementation of specific RMMs, time trends showing if and which actors implement these measures and what other options are taken are useful. Hence, if this specific information is missing, the success of specific regulations cannot be evaluated without using other information sources.

3.3.5 Targets for Improving the Information on the Conditions of Use

Overarching objective

- Ensure a common understanding of what information must be provided in ESs as a minimum, and how DUs must check and document that their use is covered by it.

Exposure drivers related to the product

- Ensure information on the average concentration of substances in products (mixtures and articles) is available to the authorities in a structured data format.

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15 Restriction process of NMP
• Enable registrants to provide the type of matrix binding of a substance in IUCLID.

Exposure drivers related to the use

• Enable provision of all relevant exposure drivers during use in IUCLID.
• Ensure PROCs and ERCs reflect the emission and exposure potential via core exposure drivers related to the processes, such as water contact, process containment etc.

Exposure drivers related to the service life

• Enable provision of all relevant exposure drivers during service life in IUCLID.
• Review whether PROCs and ERCs should be refined to better reflect (different) exposure potentials during service life with some core exposure drivers that are relevant to articles.

Operational conditions and risk management measures

• Ensure information from the CSR describing the use and the applied RMMs is available in a structured data format to the authorities.

3.4 Information on Emissions

Information on emissions supports the understanding of the potential pressure on the environment from a substance as such or the contribution of individual uses to the total environmental releases. Information on emissions include:

• Release rates from a product or a process to the environment (water, air, soil)
• Modelled/measured emitted amounts from products or processes to the environment (water, air, soil).

3.4.1 Information Needs for the Regulatory Processes

Information on emissions is mainly needed to support the development and justification of (specific) restrictions and the monitoring of the impacts of a regulatory measure. The ARN does not rely on this information.

Assessment of regulatory needs

The ARN is currently based on the use pattern and tonnage information. If reliable information were available on migration or release rates from products or processes, or total emitted amounts, it could be used as supportive information. No explicit need for this information was observed in the analysis.

Restrictions

Information on emissions is mainly needed for drafting specific restriction proposals, as generic restrictions under Art. 68(2)/GRA do not require a risk assessment\(^\text{16}\). The authorities may use migration/release rates from products and processes as input to emission models or use the emitted amounts reported per use in the CSRs for either the demonstration of risks or, for non-threshold

\(^{16}\) It is currently unclear whether the future decision making on derogations from generic restrictions will only rely on the demonstration that a use is considered essential, or whether emission and exposure considerations could also justify a derogation. In the latter case, some emission information may be relevant also under the GRA. The outcome of the study on the reform of the restriction process and the authorisation scheme may provide further insight into this.
substances, to define the current emission situation. Measured data on emitted amounts can substantiate modelled data or be used in the assessment as such.

Measured or modelled emission data supports the demonstration of (which) uses are not adequately controlled and require addressing, and are the basis for developing benefit estimates or cost-effectiveness ratios of a potential regulatory measure.

**Monitoring impacts of regulatory measures**

Time trends on the total environmental emissions and emissions from the products or processes addressed by a regulatory measure are needed to check if it is effective. This information is most important for PBT/vPvBs but might be more reliable than exposure data also for other substances.

### 3.4.2 Availability and Quality of Information on Emissions

**Registration dossiers**

<table>
<thead>
<tr>
<th>Information type</th>
<th>Availability in the registration dossier and observed shortcomings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Release rates from processes</td>
<td>Default values from ERCs are too conservative and the application of the categories is partly inconsistent, SPERCs do not cover all processes, are still conservative and partly not transparently derived</td>
</tr>
<tr>
<td></td>
<td>Low release rates other than the defaults may be provided but partly with poor justification</td>
</tr>
<tr>
<td>Release rates to the environment per AC</td>
<td>Hardly any defaults are available other than the (worst case) factors in ERCs and refined but still generic factors in SPERCs</td>
</tr>
<tr>
<td></td>
<td>Migration or release rates are not normally provided based on measurements</td>
</tr>
<tr>
<td></td>
<td>A data field exists in IUCLID but it is not mandatory to fill it</td>
</tr>
<tr>
<td>Modelled total emitted amount to the environment</td>
<td>Available in structured data format in IUCLID per compartment (air, water, soil), but not mandatory</td>
</tr>
<tr>
<td></td>
<td>As information is based on CSR and the need to demonstrate safe use, information from environmental assessments is not sufficiently reliable</td>
</tr>
<tr>
<td>Measured total emitted amount to the environment</td>
<td>Not provided in the registration dossier as not available to the registrant (apart from own use)</td>
</tr>
</tbody>
</table>

**Information in other sources**

Information on releases and release rates from processes may be available for some substances in the grey and scientific literature, best available techniques reference documents (BREFs) or inspection campaigns. Some OECD emission scenario documents\(^\text{17}\) provide release rates in relation to (ranges of) substance properties. The European Industrial Emissions Portal (EEA 2021)\(^\text{18}\) includes information on releases from large installations.\(^\text{19}\) Similarly, information on migration or release rates of specific substances from specific matrices and products may be available in literature. Migration models exist to derive migration rates, e.g. for food contact materials. However, as migration rates are specific for each substance-matrix combination a few values may not cover the entire spectrum and are therefore hardly representative. Information on releases from products and processes can also be gathered through formal and informal consultations with stakeholders using the substance.

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\(^{18}\) This portal replaces the European Pollutant Release and Transfer Register website since June 2021.

\(^{19}\) As only the large installations (exceeding specific thresholds) are required to report on a limited number of pollutants, these data is not comprehensive, but potentially representative for a specific type of use (process).
3.4.3 Causes of Information Gaps and Shortcomings

**Technical issues**

- Information on release rates from products and processes are not available in structured data format from the CSR

**Availability of methods**

- The emission behaviour of substances from products and processes depends on several factors, including the type of material, the binding to the matrix, and the CoU. Therefore, a prediction via models is complex. Only for some materials, respective models are available.
- Measurement methods of release rates are missing and available only for some few applications, such as indoor air quality (e.g. emissions of volatile organic compounds from construction products must be determined using a chamber test).
- Emissions from processes are not normally determined and/or controlled substance-wise under permitting legislation but rather sum parameters are regulated and controlled, except for a few substances and substance groups.

**Knowledge in the supply chain**

As registrants are not aware of the CoU at the DUs, they are normally also not aware of the emissions from downstream products and processes. This is the main reason why no specific emission information is included in registration dossiers.

Similarly, migration and release rates of substances from products and processes are usually unknown also to the DUs. However, due to their better knowledge of the products in which a substance is applied and the CoU or type of AC it is included in, they could better determine migration or release rates for their uses. Migration and release rates as well as emitted amounts are no sensitive business information and could be communicated upstream, but this does not take place in practice.

3.4.4 Possible Consequences of Insufficient Information

**Assessment of regulatory needs**

As the ARN does not depend on emission information, information gaps or insufficient quality of this information does not hamper the process.

**Restrictions**

Authorities are likely to thoroughly analyse information on emissions in the registration dossiers and, due to the observed shortcomings, are most likely to make their own emission estimates (potentially at a higher granularity). As registrants do not provide reliable and specific (measured) emission information for downstream uses, authorities gather additional information from other sources. If authorities rely on incorrect emission information, they might wrongly weigh the relevance of uses, potentially resulting in restriction scopes that either cover too many (irrelevant) uses or do not cover enough (of the relevant) uses. The former might cause unjustified market impacts (low benefit at significant cost), while the latter might result in failure to ensure a high level of protection.

A recent example where emission information was considered insufficient is the German restriction proposal on undecafluorohexanoic acid (PFHxA), its salts and related substances (ECHA 2021). Due to a lack of socio-economic information and emission information, the SEAC concluded that the measure
is appropriate to address but could not assess whether it is the most appropriate one. By concluding on the proportionality of the measure, SEAC nevertheless recommended to implement the restriction. The Commission has not yet taken a decision on the restriction proposal.

Wrong information on emissions may cause a failure to demonstrate risk due to a lack of supportive evidence, resulting in wasted resources and potentially the continuation of problematic uses.

**Monitoring impacts of regulatory measures**

The substance amounts emitted over time are a crucial indicator of the success of a regulatory measure, in particular related to PBTs/vPvBs. Therefore, time trend information is needed to evaluate if regulation fulfils its aims.

### 3.4.5 Targets for Improving the Information on Emissions

**Release rates from processes**

- Make information on release rates from processes (including from waste treatment) available to the authorities.
- Improve (guidance on) ERCs regarding the release rates and understandability for the registrants to ensure they are applied correctly and consistently.

**Release rates from products / articles**

- Make available information on migration and release rates from matrices (articles) better accessible to the authorities.
- Better enable market actors to determine release rates of substances.

**Modelled total emitted amounts to the environment**

- Develop (more specific) emission models to determine environmental exposures.

**Measured emissions**

- Make existing information on environmental emissions accessible and generate more emission data, where this is needed.

### 3.5 Information on Exposures

Information on exposures is needed to identify the degree to which humans or the environment get in contact with hazardous substances and to compare the exposure levels to determine potential risks. Quantified exposures may be derived using exposure models or obtained from measurements. Needed information on exposures includes:

- Modelled exposures levels and
- Measured exposure levels

### 3.5.1 Information Needs for the Regulatory Processes

Information on exposures is necessary as input to the risk assessment and SEA of mainly specific restriction proposals and for evaluating whether regulation is effective (time trends). Discussions with
and written input by the RiME+ members revealed that they use information on exposures also for ARNs.²⁰

**Assessment of regulatory needs**

The ARN does not rely on quantified exposure information. No respective need was identified.

**Restrictions**

The authorities need exposure information for specific restrictions to enable demonstration of inadequate control of risks.¹⁶ As authorities frequently make their own exposure assessments when drafting restriction proposals, which frequently is more specific / granular than that of the registrants, the modelled exposure data in the registration dossiers as useful for an initial orientation but usually not sufficient to support the restriction proposal. Any relevant and representative measured exposure data, e.g. from the workplace, is useful, as the authorities have little access to it. Exposure information is also necessary to determine the baseline and improvement potential in the SEA.

**Monitoring impacts of regulatory measures**

Time trends on exposure levels help checking if a regulatory measure is effective. This may be especially relevant for measures relating to the workplace, where a direct correlation between use and exposure is possible.

### 3.5.2 Availability and Quality of Exposure Information

#### Registration dossiers

<table>
<thead>
<tr>
<th>Information type</th>
<th>Availability in registration dossiers and observed shortcomings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modelled exposure levels</td>
<td>Exposure assessments in CSRs are designed to demonstrate safe use, i.e. exposure levels are frequently close to the derived no effect levels or predicted no effect concentrations. A IUCLID data field exists to report modelled exposure levels but is not mandatory.</td>
</tr>
<tr>
<td>Measured exposure levels</td>
<td>Usually not available, if at all information of workplace exposures in the registrants’ use(s) Frequently, no contextual information is provided with the measurements, making it difficult to interpret the representativity and relevance of data. A IUCLID data field exists to report measured exposures but is not mandatory.</td>
</tr>
</tbody>
</table>

#### Information in other sources

Exposure models exist for different assessment tiers that can be used by the registrants and the authorities. Input information to the models may be emitted amounts (cf. Section 3.4 or information on the CoU cf. Section 3.3).

Measured exposure data is available in the literature and in databases, e.g. the IPCHEM which makes information from human biomonitoring and environmental monitoring accessible to the public. Monitoring data is also generated under environmental legislation, such as the Water Framework

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²⁰It was commented that more information on occupational and environmental exposures should be available in registration dossiers. Risk characterisation ratios close to 1 would be used to identify uses with potential risks.

²¹Typically via an assessment of the Conditions of Use (realistic worst case modelling to derive exposure potential).
Under OSH legislation, measurements of the workplace air are performed to ensure and document compliance with OELs. Furthermore, human biomonitoring may be performed at the workplace for certain pollutants.

The use of this information is generally possible, but some drawbacks exist. These data are mostly generated for substances which are already regulated but are missing for unregulated ones. While the IPCHEM is comparably new and does not include information from older studies, the information from workplace measurements is not standardised and accessible to authorities. As exposure levels of the general population rather indicate long-term trends and can hardly be related to a particular use, process or product, they are not useful to assess or justify specific aspects or measures. Exposure data is normally not use-specific and/or provided for certain sub-groups of the population/work force, which may be relevant to justify specific restrictions.

3.5.3 Causes of Information Gaps and Shortcomings

Technical issues

Information on exposure levels is in IUCLID but is not mandatory.

Knowledge in the supply chain

Except for their own use, registrants mostly perform generic CSAs with the aim of demonstrating safe use. The resulting exposure levels of humans and the environment do not necessarily reflect those occurring in practice. The registrants have no detailed information on the exposures downstream.23

DUs should model and assess workplace exposures as part of the workplace risk assessment. However, the OSH obligations are not always implemented to a full extent and measured data from OSH are only available, if at all, for substances with EU and/or national OELs. Biomonitoring data should be available for (some) CM substances handled at workplaces but is not available in a structured and electronic format.

DUs are not normally aware of environmental exposure levels, except in their own wastewater (before the wastewater treatment plant or at the point of discharge, where these are directly emitted to surface waters). No requirements exist for the downstream users to determine exposure levels of used substances in the environment.

Some companies may assess potential consumer exposures from articles to ensure product safety under the General Product Safety Directive24, which requires products placed on the market to be safe during normal and foreseeable use. However, there is no legally defined methodology under this legislation.

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23 A Member State reported, that in some cases the assessment of CSRs with risk characterisation ratios close to 1 showed that uses were partly described in an unclear manner and the logics of input parameters to exposure models were difficult to follow. Upon request, the input parameters were modified to demonstrate safe use, leaving the impression of the exposure assessment being arbitrary. While not being representative, the case may underline that the authorities consider the exposure information in registrations as uncertain.
3.5.4 Possible Consequences of Insufficient Information

Assessment of regulatory needs

As the ARN does not depend on quantified exposure information, data gaps or insufficient data quality of that information in registration dossiers does not hamper the process.

Restrictions

Due to the CSRs not necessarily reflecting exposure levels in practice, authorities usually base their specific restriction proposals on their own exposure assessments. Therefore, they rather need good input data to estimate exposures (cf. Section 3.3 on CoU and Section 3.4 on emissions) than on modelled exposure levels as such. Measured exposure data are supportive evidence for the justification of a restriction but it is often unclear how representative the data are.

If the authorities rely on incorrect exposure information, similar consequences may occur as described for insufficient emission information. They might wrongly evaluate the relevance of uses, potentially resulting in restriction scopes that either cover too many (irrelevant) or do not cover enough (of the relevant) uses. The former might cause disproportionate market impacts (low benefit, high cost), while the latter might result in failure to ensure a high level of protection.

The phthalates restriction showed that biomonitoring data can play an essential role in demonstrating the existence of risks that are not adequately controlled. While the first restriction proposal failed to convince the RAC of the need for regulatory action (ECHA 2012), the second proposal, which included recent biomonitoring data showing significant exposure levels in humans (ECHA 2017). If that information had been provided already for developing the first proposal, resources could have been saved and the restriction be passed earlier, i.e. the level of protection be increased earlier.  

Monitoring impacts of regulatory measures

A lack of information on exposure levels may hinder evaluating the success of regulatory measures, specifically where workers health should be improved. Here, the exposure levels (including internal exposures) are a good indicator of whether a measure achieves its goal. In the field of consumer and environmental protection, the policy success monitoring via exposures is challenging due to the many factors influencing a substances existence in humans and the environment. Measured data closely relate to the aim of regulation – preventing chemicals-related diseases and environmental pollution.

3.5.5 Targets for Improving the Information on Exposures

Modelled exposure levels

- The improvement needs relate to the input information to exposure models rather than modelled data as such (cf. Sections 3.3 and Section 3.4).

Measured exposure levels

- Make measured exposure data better accessible to the authorities, e.g. by increasing the content of the IPCHEM from other sources.

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25 Restriction process of four phthalates
3.6 Synergies with other legislation

In the discussions at the RIME+ meeting as well as according to some written comments received after the meeting it was emphasized that more synergies could be created through better use and exchange of information between REACH and OSH legislation as well as between REACH and the Industrial Emissions Directive and the Water Framework Directive. Data from workplace measurements and biomonitoring by employers could support the prioritisation of the need to regulate substances in industrial and potentially also professional uses. Emission reporting under the IED, apart from not being fully implemented in the industries, could provide additional information for prioritising environmental action needs. Vice versa, the registration data could help authorities in permitting and enforcement actions. If the authorities knew that companies use or produce certain substances, they could better assess if certain emissions should be reported under the IED, for example. Furthermore, REACH information on the CoU, emissions and exposures could be used to develop BREFs. While having been discussed on several occasions as an opportunity and improvement need regarding the interaction of legislation and overall policy integration, these aspects are not further discussed in the study.
4 Summary of information needs and information gaps

The aim of Task 1 is to analyse the authorities’ information needs to manage risks from chemicals, to identify what of the needed information is currently available at a sufficient quality and granularity and to describe what information gaps exist. The analysis covers the assessment of regulatory needs (ARN), the prioritisation of SVHCs for authorisation, the drafting of restriction proposals and the (ex post) monitoring of the impacts of regulation.

The assessment of information needs was based on public literature, information provided by ECHA, the contractor’s experience as well as input from a RiME+ meeting (9 December 2021), where the interim results of the gap analysis were presented. The assessment of information availability focussed on what is provided in the registration dossiers (IUCLID and Chesar), an analysis of the ‘typical’ knowledge of the registrants about the downstream uses as well as the availability of information in additional information sources, such as the grey literature, the SCIP database or DU notifications. The main causes of information gaps were described, and consequences of missing information mechanistically derived for each of the assessed regulatory processes. Based on this analysis, improvement objectives were defined for the various types of use and exposure information.

4.1 Use pattern

Knowledge of the use pattern, including information on the relevant life cycle stages (LCs), the technical function (TF) of a substance and whether it is intended to transform, the products (mixtures and articles) a substance is used in, is needed for all regulatory processes.

For the ARN, information on a substance’s use pattern supports the identification if a use is widespread (or localised) indicating exposure potentials and risk management capacities of the substance users. Information on the TF allows to identify if substances could be used as an alternative for another and hence, supports consistent regulation that prevents regrettable substitution. Furthermore, the use pattern allows understanding what uses should be addressed under REACH and what uses are subject to other legislation. Information on the use pattern also helps identifying appropriate regulatory instruments, considering existing legislation and potential exemptions from REACH instruments. Information on the use pattern indicates potential impacts of regulation on the market actors in terms of the number and types of affected products, processes and sectors.

If the ARN is based on incomplete, missing, or outdated information on a substance’s use pattern the consequences may be that a high level of protection cannot be ensured due to overlooking regulatory candidates or due to overlooking relevant uses when designing a regulatory measure. It is also possible that substances or specific uses are regulated, which do not pose relevant risks, whereby resources would be spent inefficiently and risk management of more relevant substances or uses could be delayed. As the ARN is not an in-depth risk assessment and is based mainly on the registration dossiers, information from additional information sources is unlikely to correct inappropriate decisions at this stage.

For drafting any type of restriction proposal, information on the use pattern is necessary to rank the uses (including regarding the occurrence in articles) that should be regulated. It is needed to scope a restriction and define its conditions (what products and/or processes should be covered and how). For restrictions under Art. 68(1) or 69(2) (specific restrictions), the use pattern information is also needed to support the identification and assessment of alternatives and the potential impacts of the restriction. For generic restrictions according to REACh Art. 68(2) and the potential for increased use of GRA in the future, the information as currently provided in registrations is considered not sufficient with a view to the need to prioritise (specific) article types. Specific restriction proposals according to
REACH Art. 68(1) or (the assessment of a need to make a restriction under) Art. 69(2) may need more granular use information, specifically regarding the product and article types a substance is used in.

If information on the use pattern is missing, inconsistent or outdated in the registration dossiers, authorities may overlook relevant uses or restrict uses with only a minor contribution to the overall risk. The former could result in a failure to ensure a high level of protection and the later in inefficient regulation. As the restriction process is staged, usually authorities analyse literature and databases to gather additional information, and (formally) consult stakeholders. Therefore, the registration dossiers are only the starting point for the restriction proposals and hence, the thereon-based initial understanding of the use pattern may be corrected in the process. However, additional information collection upon the initiative of the ECHA or the MSs is less transparent and more time consuming than if the information were available from registration dossiers.

Information on how the use pattern of a regulated substance changes over time is an important indicator how a regulatory measure impacts on the market. This is even more helpful if related to the tonnage applied in a certain use (cf. below). For example, if the use of a substance is banned in consumer mixtures, this should be visible in the use pattern immediately after the ban enters into force. To discern regulatory impacts from market trends that started already before a measure, it is necessary to have time trend information on the use pattern over a longer time period (e.g. to account for announcement effects, other events impacting on the use, such as the availability of a good alternative).

If information on the use pattern is missing, inconsistent and not available as time trend in the registration dossiers, the impact of a regulatory measure on the uses as identified by the registrants cannot be sufficiently well evaluated. Additional information on use patterns / market data may be available only for some (commodity) substances and would therefore have to be specifically generated.

Information on the relevant life cycle stages, technical function, and the PCs and ACs according to ECHA’s guidance R.12 are generally provided in the registration dossiers. Observed deficits concern the completeness of information where data is not subject to the TCC (e.g. PCs for industrial and professional uses), inconsistencies and ambiguities in registration dossiers and a lack of relationships between the TF, PCs and ACs, which hampers the understanding of the use pattern. Furthermore, information in the registration dossiers is partly outdated.

The most important reasons for incomplete, outdated, or inconsistent information on the use pattern are:

- The registrants are not sufficiently aware of the uses downstream and frequently base their use description on the generic sector use maps, which may be complemented from the sales statistics. As the communication up the supply chain does not work sufficiently well, registrants do not receive corrective information from their customers.
- The requirements on ESs do not clearly define how broad a use may be described, but it is up to the registrant to define the scope as needed. Frequently several TFs and PCs or ACs are covered in one scenario, as broad scenarios are most efficient for CSA. However, this prevents a clear understanding of the use.
- No requirement exists to regularly update the registration dossier, including the use pattern.
- The use descriptors, guidance documents and industry tools (specifically the use maps) are not fully aligned with the regulatory needs and the language in the market.
- Not all legally required information is subject to the TCC.
As the information on use patterns is crucial at the initial stage of the regulatory risk management processes and relevant for drafting restriction proposals and monitoring policy success, an improvement of the information is considered as highest priority. Improvement options should therefore ensure that:

- ECHA and the MSs obtain reliable, complete, and up-to-date information on the user groups of a substance (industrial, professional and consumers) and the existence of an article service life from the registration dossiers
- The registration dossiers enable the authorities to get a comprehensive understanding about the PCs in which a substance may be used, what specific TF it fulfils (in a specific PC or AC), and whether some uses are covered by existing legislation
- The registration dossiers allow understanding if a substance transforms along its life cycle
- The registration dossier should provide information on in which ACs it occurs
- Authorities should have access to more specific information on the specific mixtures and articles a substance is used in to draft (specific) restriction proposals.

4.2 Tonnages

Information on the consumption tonnage of a substance and the tonnage breakdown into (groups of) uses is needed for all regulatory processes.

In the assessment of regulatory needs, the consumption tonnage indicates an overall exposure potential, while the tonnages entering (groups of) uses can be used to weigh the relevance of uses (and their exposure potentials). Consequently, tonnage information supports the prioritisation of substances and uses for regulatory action and helps identifying regulatory instruments that would address the main potential risks.

If tonnage information is missing and/or not up-to-date, the prioritisation of regulatory actions and the selection of the regulatory instruments may be misguided. Among the consequences may be that uses with significant exposures are deprioritised (failure to ensure a high level of protection) against uses with a seemingly higher exposure potential based on use tonnage, resulting in overlooking substances that need regulation while identifying substances as priority that do not need immediate action. Furthermore, inadequate regulatory instruments may be selected that cover only minor uses and/or aim to regulate uses which do not need to be addressed.

For drafting restriction proposals, the overall consumption tonnages, and tonnages per (groups of) use are good starting points. For generic restrictions according to REACH Art. 68(2), the available information required according to the current provisions of REACH may be sufficient to prioritise substances and products for which action is needed and to roughly understand the potential regulatory impacts. More granular information may be needed for scoping generic restrictions, in particular for articles.

For specific restrictions under REACH Art. 68(1) or to assess the need for a restriction according to REACH Art. 69(2), more granular information is needed to identify and demonstrate that risks (from articles) are not adequately controlled and to make a SEA. Tonnage information may be needed at a higher or lower granularity than the current use descriptors for PCs and ACs, depending on the hazard of a substance, the scope of the restriction and the planned restriction conditions.

If information on tonnages is missing or not up-to-date, the authorities may start their restriction proposals with a wrong anticipation of the relevance of uses and exposure potentials. This may result in restriction scopes that fail to address uses that most contribute to the overall risks (which may result...
in a failure to justify the restriction) or that cover uses which do not significantly contribute to the overall risk, thus creating compliance costs without a clear benefit.

Due to the iterative nature of the restriction process, wrong initial assumptions may be corrected during the assessment of additional information and gathering of stakeholder comments. However, as tonnage information on uses is hardly available from other information sources and not necessarily known to the stakeholders (or only in parts), a wrong weighing of uses may remain undetected.

Information on how the amounts of a regulated substance applied in (groups of uses) change over time is an important indicator of the market impacts of a regulatory measure, as discussed in relation to the use pattern (c.f. above). If information on tonnages is missing or not up-to-date and available as time trend in the registration dossiers, the impact of regulation on the uses as identified by the registrants cannot be sufficiently evaluated. Additional information to evaluate the regulatory impacts based on other data sources may be available only for some (commodity) substances and would therefore have to be specifically generated.

Information on the registration tonnage is provided in the registration dossier. The amounts used as intermediates and the amounts immediately exported by the registrants is sometimes but not always provided. The tonnage breakdown per use and service life is available in the registration dossier and derived per ES as part of the environmental exposure assessment. The tonnage used per LCS can be provided as aggregated amount from all relevant ESs. An amount per PC or AC is available only if an ES covers only one PC or one AC.

The main shortcomings of tonnage information in the registration dossiers concern are that specific tonnage data per (groups of) use are missing or inconsistent with the total registration tonnage. In addition, data on exported amounts by the registrants and about uses as intermediates are incomplete.

The most important reasons for incomplete, outdated, or inconsistent information on tonnages are:

- The registrants are not sufficiently aware of the downstream uses and the tonnage fractions entering (groups of) uses.
- Tonnage information is confidential and not communicated upstream.
- The tonnages per LCS or per use/service life used to assess environmental exposures in the CSA may not reflect the use amounts in the market.
- It is not required to regularly update the tonnage information in the registration dossier.
- Not all legally required information is subject to the TCC (exported amounts, intermediates).

Information on tonnages (per use) are important exposure proxies for the assessment of regulatory needs, including the recommendation of SVHCs for inclusion in the authorisation process. Compared to the use pattern data, tonnage data is considered less important for the ARN because it is only used to refine the assessment by weighing the relevance of uses against each other based on tonnage. However, specific tonnage data per use is crucial for the development of specific restriction proposals. The ability to monitor policy impacts strongly depends on time trends of the registration and use tonnages of substances. As a minimum, changes in the total tonnage over time are needed but. However, to enable a differentiated view on changes in the use pattern, more differentiated tonnage information per use as time trends are needed.
Improvement options should ensure that:

- ECHA and the MS obtain reliable, complete, and up-to-date information on the consumption volume of substances on the EU market from the registration dossier
- The registrants specify the tonnage breakdown per (groups of) use based on their market knowledge, in addition to the volumes provided as input to the exposure assessments
- Authorities get access to more specific tonnage data at a high granularity regarding the products and articles a substance is used in, including from the DUs, to develop specific restriction proposals.

4.3 Conditions of Use (CoU)

The CoU include product – specific information, such as the average concentration of a substance in a mixture or article, or how it is bound to a matrix, process specific information, such as the exposure driving factors including processing temperature and level of containment, as well as information on the overall operational conditions and RMMs applied in a use and during service life.

In the ARN, information on the CoU is not essential. However, knowledge of relevant exposure proxies (e.g. average concentration in products) could improve the identification of regulatory candidates. In general, the ARN is not significantly hampered by a lack of or inconsistent information on the CoU in the registration dossier.

For generic restrictions according to REACH Art. 68(2), both currently and under the future GRA the information on CoU is not necessary. However, also here, information on the average concentration of substances in products/articles and the way they are bound to matrices may influence the prioritisation of substances and uses/products that could be subject to a generic restriction.

For specific restrictions under REACH Art. 68(1) or to assess the need for a restriction according to REACH Art. 69(2), information on the CoU is needed to identify and demonstrate that risks (from articles) are not adequately controlled. The information is needed as input to emission and exposure assessments and, where this is relevant, to define specific restriction conditions, such as concentration thresholds in mixtures or articles, RMMs at workplaces, or migration limits. Furthermore, information on the CoU is needed to identify impacts of a restriction and identify if emissions are already minimised and what reduction potentials exist. The granularity of needed information depends on the substance hazard, the restriction scope, and the intended restriction conditions, and is frequently needed at a higher level of granularity than provided in the registration dossiers.

If information on the CoU is missing, unspecific and/or not up-to-date, the authorities may start their restriction proposals with a wrong anticipation of the conditions applied in the market. Unless they verify and complement the registration information via a literature review, formal or informal consultations with industries and alike, the restriction proposal may be developed using that wrong information in the risk assessment and SEA. This may result in a failure to justify a restriction despite an existing risk (lack of supportive evidence, waste of resources) inappropriate scopes and conditions of a restriction and/or the coverage of too many or too few uses to address the risks appropriately. Eventually, the market actors may have to substitute despite low risks or may continue the use of a substance despite high risks (wrong restriction scope).

Due to the iterative nature of the restriction process, wrong initial assumptions may be corrected during the assessment of additional information and gathering of stakeholder comments. However, as it cannot always be ensured that the relevant stakeholders are involved and provide information to the authorities, the wrong input data to the risk assessment may remain undetected.
Information on the CoU is not normally needed to monitor the success of regulatory measures. An exemption are cases, where the regulatory measure aims to change the CoU, e.g. at the workplace. If the measure targets the use of a substance in products, market data are more likely to provide a good picture of the impacts (c.f. above).

Information on the CoU is provided per use in the ESs and for all contributing scenarios. In many cases, the registrants apply generic exposure assessment tools, such as the sector use maps, which include PROCs, ERCs and SPERCs as well as SWEDs and SCEDs in combination with Chesar and/or ECETOC TRA. Where no safe use can be demonstrated, these conditions may be iterated until the risk characterisation ratio is below 1.

The information on the CoU in the registration dossiers is derived from ECHA’s ERCs and/or the sector organisations’ SWEDs, SCEDs, SPERCs and use maps. It is the intention by using these tools that CoU are defined to cover many uses in few models. However, the downside of this is that specificities of uses are not reflected but ‘hidden’ under the worst-case emission rates related to a use. Therefore, and as the upstream communication on the CoU does not work well, the authorities do not rely on the information provided in the CSRs. In addition, only some information on the CoU is available in structured data format in IUCLID.

Information on the (change over time of) CoU may support the assessment of regulatory needs and the monitoring of policy impacts but are of low priority. However, this information is of high relevance for drafting (specific) restriction proposals as part of the justification (demonstration of risks) to scope a restriction, define restriction conditions and to assess impacts of a restriction in the market. Therefore, this type of information is not a high priority for improvement options related to the registration dossier but rather for additional mechanisms to gather information to support restriction processes.

Improvement options regarding the information basis on CoU should ensure that:

- ECHA and the MS get access to stakeholders who know specific conditions of a certain use and are enabled to request the information they need to draft a restriction
- Information on CoU that might be useful for the ARN and the monitoring of policy impacts is made available from the CSRs in a structured data format.

4.4 Emissions and Exposures

Information on emissions and exposures include data that can be used as input to emission and exposure models, such as migration rates from matrices or release rates from products and processes, as well as quantified emissions and exposures sourced from modelling or based on measurements (environmental and (human) biomonitoring, workplace measurements).

The ARN does not rely on quantified emission and exposure information. If reliable migration or release rates were available, they might be used to refine the initial understanding of exposure potentials. However, shortcomings in emission and exposure data in the registration dossier do not hamper the ARN.

Likewise, generic restrictions according to REACH Art. 68(2) in the current or future scope of GRA do not rely on this information but may use (reliable) migration or release rates to prioritise uses for regulation.

For specific restrictions under REACH Art. 68(1) or to assess the need for a restriction according to REACH Art. 69(2), mainly information that can be used as input to emission and exposure models are
needed, as normally the authorities do not rely on the registrants’ CSRs but make their own (more specified) emission estimation and exposure assessment. In addition, reported (measured) emission data as well as measured exposure levels in humans and the environment are needed to substantiate restriction proposals and broaden the evidence basis to justify a restriction as well as to estimate market impacts and improvement (benefit) potentials generated by a restriction.

If information on emissions and exposures is missing, inconsistent or wrong in the registration dossiers and is not corrected by additional data collection by the authorities from the literature or during consultations etc. a restriction proposal may lack supportive evidence to demonstrate lack of control of an existing risk (failure to ensure level of protection) or may identify risks which do not occur in reality (inefficient regulation as the use does not contribute to the overall risk). This may result in an inappropriate scoping of restrictions and the estimation of unrealistic benefits of a measure.

Due to the iterative nature of the restriction process, wrong initial assumptions may be corrected by additional information from databases, literature and stakeholder consultations. However, as it cannot always be ensured that the relevant stakeholders are involved, have the needed information (e.g. migration rates) and/or provide it to the authorities, the wrong information basis upon which the restriction is based may (in parts) remain undetected.

The change of emitted amounts and/or exposure levels of humans and the environment is an indicator of policy success. Apart from external exposures at the workplace, it is difficult to relate changes in exposure levels in consumers and the environment to a specific measure if that is not a ban or far-reaching restriction. This is due to the many sources and factors that influence the use, emission and exposure levels over time. However, if no emission (PBT/vPvBs) and exposure information (other hazards) is available, it cannot be assessed if regulation improves human health and prevents environmental pollution.

The main shortcomings regarding emission and exposure information in the registration dossiers are due to the registrants being unaware of the downstream uses and related emission and exposures, except as generically derived in the CSR. Emission and exposure information is not normally provided upstream, and the DUs also frequently do not have this information.

Information on emissions and exposures is mainly available in other information sources for substances that are already regulated (e.g. emissions published on the European Industrial Emissions Portal monitoring of surface waters under the Water Framework Directive). Measured substance-specific exposure data is also not normally available to the DUs for their own uses or the article service life. Information on external and internal exposure levels of workers from workplace risk assessments are only available at company level and, in some MSs also at the level of occupational health insurance organisations. However, this data is not standardised and its representativeness is unclear.

Improvement options regarding the information basis on emissions and exposures should ensure that:

- ECHA and the MS get access to substance-specific migration and release rates either in the registration dossier (from the CSA, where available), or from reliable and specific emission models
- Available information on measured emission and exposures is made accessible to the authorities and reviewed regarding future optimised data generation (standardisation, linking to use conditions and/or products) and use.
5 Development and overview of Policy Options for Impact Assessment

5.1 Long list of policy options

The information needs and gap assessment showed that the implementation of regulatory risk assessment and management processes would benefit from the availability of better information on uses and exposures in terms of completeness, consistency, reliability and granularity. An improved information basis of a substance’s use pattern and use volumes, as well as additional exposure proxies from the description of the use pattern and the CoU would facilitate all regulatory processes. More specific and reliable information on the CoU, quantified emissions and measured exposure data are mainly needed for priority setting on what uses to regulate, to support the demonstration of risks to justify restriction proposals, and to better understand the impacts of a restriction in the market.

Based on the assessment of information gaps and deficits in the consistency and quality of information as well as the main causes of these, a long list of policy options was developed (cf. Annex 3). The long list includes any possible option that would address the identified shortcomings, regardless of the feasibility, efforts and expected ability to improve the current information availability.

In a second step the long list of improvement options was qualitatively assessed to determine whether an option:

- Is in conflict with existing legal requirements outside REACH, e.g. competition law
- Would require provision of information from the market that registrants are unlikely to have, e.g. registrants do not normally know the use of their substances in specific articles and could obtain this information only if they and additional actors invest considerable resources
- Is in line with the aims of the Chemicals Strategy for Sustainability as well as the intended distribution of responsibilities under REACH26 and are thus expected to get general political justification and support.

Considering these aspects, all options of the long list were evaluated with regard to their likely feasibility, conformity with the REACH principles and expected benefits as well as the scale of possibly associated implementation efforts. Based on this rough evaluation, the options that qualified as ‘potentially feasible’ were compiled and modified so as to derive a set of options that would address all relevant information needs with a focus on information needed for the ARN. The initial proposal was revised after discussion with ECHA and the Commission.

The options in the long list can be assigned to one of the following types of options:

1) **Optimisation of implementation tools** (based on Article 111 of REACH) to improve the level of detail, consistency and accessibility of information on use and exposure to the authorities. The technical optimisation includes several aspects within the current system, can be implemented without legal changes27 and are based on improvements of guidance, changes

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26 In particular that industry is and remains responsible to ensure safe use of chemicals while the authorities’ regulatory risk management activities complement this as a ‘safety net’; the burden of proof for chemical safety is on the industry, the industry shares responsibility for safe use in the supply chain etc.

27 For some of the technical optimisations it could not be finally identified whether a concretisation of REACH Annex VI is necessary to back up an option. For example, the inclusion of a IUCLID data field to flag that a substance is intended to transform during use and subjecting the submission of such information to the TCC might require specification in Annex VI that this information is an inherent part of the use description. Up to now, this type of information is mainly required in Annex I as part of the chemical safety assessment.
in the IUCLID data structure and the use of IT-instruments, as well as the organisation of information in the IUCLID file.

2) Definition of new or change of existing requirements for the registrants to provide use and exposure information (including on tonnage) in the registration dossier and to update registration dossiers on a regular basis or upon a regulatory trigger. These options extend beyond the current system and hence require changes either to the REACH enacting terms or Annex I or Annex VI.

3) Definition of new or change of existing requirements for DUs to communicate use and exposure information upstream. These options extend beyond the current system and would hence require changes to the REACH enacting terms.

4) Definition of obligations for DUs to report use and exposure information to the authorities. These options go beyond the current system and may require the extension of existing or the introduction of new information mechanisms under REACH.

5) Improved use and accessibility of existing information from ‘other sources’, such as the PCNs, national information sources or monitoring data. These options may require changes in other legislation to make the information accessible (e.g. the use of PCN data requires a change of the classification and labelling regulation) but do not go beyond the REACH current system.

6) Change of the design of regulatory processes, in particular the restriction process, to eliminate the need for information on uses and exposures of the authorities. These options go beyond the current system and would require changes in the REACH enacting terms.

5.2 Exclusion of certain improvement options

Options falling under the bullet points 3, 5 and 6, i.e. aiming to improve the upstream communication in the supply chain, the use of existing information or changes to regulatory processes to avoid certain information needs, were excluded from the list of options to be carried forward to the impact assessment. The following sections briefly explain, why these options were excluded.

5.2.1 Upstream supply chain communication

REACH Art. 34 requires DUs to provide “any other information that might call into question the appropriateness of the Risk Management Measures (RMMs) identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.” This explicit obligation for upstream communication is triggered by the receipt of an SDS with ‘inappropriate’ RMMs.

REACH Art. 37(1) specifies the right of DUs to provide information on their use to support a registration (Art. 37(1)) or to make a use known to their suppliers with the aim of the use being made an identified use (Art. 37(2)). To enable the use identification, as a minimum a “brief general description of use” should be provided to the supplier.

A DU who receives an SDS and/or ES, which does not cover his CoU, has several options to act: cease the use, implement the recommended CoU, search another supplier with an ES that covers his use, make a DU CSR, or communicate their CoU upstream with the aim of having the CSA modified accordingly and the CoU communicated back to him with the result of being covered. Hence, the downstream communication may also trigger an upstream communication.
It is common to all of these mechanisms that:

a) DUs react to information from their supplier, i.e. another company (business to business communication)
b) The communication is triggered by CoU but not by information on PCs or ACs
c) The content of (potentially) triggered upstream communication concerns the CoU but not the PCs or ACs.

The upstream communication up through the supply chain is commonly evaluated as not functioning (e.g. REACH Review 2018). Among the reasons are that a) the communication trigger is not sufficiently clear (what is an ‘inappropriate risk management measure’, how can it be determined if a use is covered), b) (communication) efforts do not create (significant) benefits and are therefore of low priority in general, c) there is no enforcement and d) the approach to nanoforms (it should be clarified that, where not explicitly covered, it should be treated as use advised against).

The development plan for the REACH Review Action 3 includes several activities to improve the downstream communication by further standardising and by digitalising communication, in particular via the SDS and ES. This will also influence the frequency and quality of upstream communication but is unlikely to significantly improve the registrants’ knowledge about his substance’s use pattern.

Any approach to improve registration dossiers via upstream communication implies that the DU communicates / forwards relevant information upstream that the registrant is able to understand and process for his registration, i.e. by identifying additional uses, specifying relevant PCs. The feasibility of this improvement mechanism is generally questioned because:

- The current provisions under REACH (and their implementation by the industry) have failed to trigger relevant and useful upstream communication.
- DUs generally have a low interest in sharing use (and tonnage) information upstream, as it is considered confidential and there might be no benefits related to it.
- Even if DUs provided information on the PCs/ACs they include a substance into, it might not be processable by the registrant due to the mere amount of communication (unless effective data processing tools are established).
- Competition law is likely to prohibit exchange of (some) market information along the supply chain.
- Overcoming the lack of incentives to communicate upstream by implementing legal requirements is not feasible due to a lack of enforceability of business to business communication (especially considering that there are already strong regulatory incentives to have one’s use identified).

Therefore, no option aimed at improving the upstream communication along the supply chains is suggested for the further impact assessment.

### 5.2.2 Improved use of existing information

Options under bullet point 5 ‘improved use of existing information’ may be relevant for the ARN or the monitoring of policy success, but mainly concerns the information gathering for drafting restriction proposals. Most of the analysed information sources are accessible to the authorities. Some of the sources are already in the hands of ECHA (SCIP\(^{28}\), DU notifications) and are already used in drafting restrictions. Others are in the hands of other agencies or the MSs. The most important improvement potential was identified in the use of data reported for poison information centers, which includes

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information on the PCs in high granularity. Due to the different purpose of the PCN database it contains only some types of mixtures (i.e. mixtures classified as hazardous for human health), but generally, that knowledge would be very valuable to the authorities regarding the use pattern. Making this information source available would require a change of the CLP regulation and is thus out of the scope of the REACH review.

To make external information sources more useful and reduce the efforts to obtain relevant data, approaches to harmonise data structures (e.g. alignment of reporting categories in production statistics29) or data bases (e.g. SPIN database30) would be helpful but appear cumbersome and not justified with a view to the (few) cases, where detailed information from these sources is needed. However, there may be data needs from other areas contributing to the need for more harmonised and accessible information to which the REACH information needs may add up.

Information gaps and deficits in policy integration primarily between chemicals and installation-related legislation were identified in the RiME+ discussions and written inputs to the project team. Comments stressed the wish or need to create synergies in the use of use and exposure information from REACH for other policies and vice versa.

While the analysis of options to use additional use and exposure data to support the ARN and the drafting of restriction proposals under REACH is considered valuable, no option qualified for being included in the impact assessment. It is assumed that the use of external information sources will remain an important but case-specific element of information gathering, which can hardly be improved by measures under REACH.

5.2.3 Changed design of regulatory processes

The ‘change of the design of regulatory processes’ concerns the restriction process (and potentially a reform of the authorisation), where a shift of the burden of proof, similar as envisaged for the GRA (restrictions as currently initiated on the basis of Article 68(2)) could significantly reduce the authorities’ need for use and exposure information. There would, however, still be information needs similar to Option 4 considered in Sections 6 and 7 of this study.

5.3 Overview of the options taken forward

Table 5-1 provides a high-level summary of the policy options and their main components/sub-options that are being considered in the Impact Assessment under this study. The options can be implemented independently of each other or combined in different ways. Most of the options are mutually exclusive but certain elements of Options 3 and 4 overlap.

<table>
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<tr>
<th>Table 5-1: High-level summary of the policy options for improving information on uses and exposures under REACH</th>
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<td><strong>Option 1: Technical optimisations (potentially requiring changes in Annex VI)</strong></td>
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<tr>
<td>• Improved guidance, use descriptors and explanation of terms31</td>
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<td>• Additional IUCLID data fields</td>
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<td>• Obligatory use of Chesar/import of information from the CSR (Chemical Safety Report)</td>
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<td>• More detailed and unambiguous allocation of TFs (Technical Functions) to PCs/ACs (Product Categories/Article Categories) and of PCs to uses</td>
</tr>
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<td><strong>Option 2: New requirements to provide more differentiated tonnage information in the registration dossier and new requirements on dossier updates</strong></td>
</tr>
</tbody>
</table>

30 http://spin2000.net/
31 Potentially including a clarification that transformation includes changes to nanoforms.
Table 5-1: High-level summary of the policy options for improving information on uses and exposures under REACH

- Provision of tonnage information on a regular basis regarding
  - Total annual manufacturing and import tonnage (as such or in mixtures)
  - Total tonnage exported by the registrant (per year)
  - Total tonnage applied as an intermediate

Option 3: Regular reporting by downstream users of their use of hazardous substances to ECHA

- Regular notification by DUs on the substances they use, two sub-options: reporting under the current approach to Candidate Listing and for substances of concern under the Generic Approach to Risk Assessment (GRA)
- Applies to both mixture and article producers
- Use & tonnage data reported
- Potential variations: greater scope in terms of more substances, company tonnage use thresholds exempting reporting, etc.

Option 4: New registrant and downstream users’ duty to provide information prior to regulatory action (one-off)

- Update of the full registration dossier prior to regulatory action
- Provision of information by downstream users directly to ECHA (similar to Option 3 but one-off)

All four options aim at obtaining better information on the use pattern, related exposure proxies (such as consumer vs professional vs industrial use) and exposure information inherent to a use, and the registration tonnage and tonnage breakdown per (groups of) uses.

5.3.1 Option 1: Technical optimisation

REACH requires the inclusion of use and exposure information into the registration dossier. Annex VI, ECHA’s guidance documents and the existing IT implementation tools, namely the IUCLID and Chesar specify the information requirements. The assessment of the availability if information suggests that there are several improvements that could be implemented either without legal changes or ‘only’ requiring a concretisation of the information requirements in Annex VI (which can be done by comitology). These technical optimisation interventions aim at making more information from the Chemical Safety Reports (CSRs) available for automated extraction and evaluation, obtaining all legally required information from the registrants and decreasing uncertainties about the reliability and meaning of information by removing ambiguities in the guidance and picklists.

In addition to the mainly technical changes, it is suggested to assess the possibility of further differentiating the use description in the CSR and IUCLID by requiring a more specific and unambiguous allocation of use descriptors to specific uses in the CSR, which would be reflected in the life cycle tree. The aim of this option is to provide the authorities with a clearer understanding of the relations between use descriptors.

5.3.2 Option 2: New requirements to provide more differentiated tonnage information in the registration dossier and to regularly update it

Based on the assessment (in this study) of information available to the registrants, it is not considered feasible to request much more information from registrants on downstream uses than currently required. As no realistic option was identified to improve the upstream communication so that registrants would receive better information on uses and exposures from their DUs, no additional information requirements are suggested for the impact assessment that would be based on an improved upstream communication.
It is considered possible for the registrants, however, to further specify information on consumption tonnages, as well as on the split of their total production volume according to (groups of) uses. The level of granularity of the information and the grouping of uses depend on whether the current use descriptor system is used or if Option 1 is implemented.

At present, information on the production and/or import tonnage of substances must be updated in the registration dossier only if the tonnage band is changed. Whilst some registrants provide tonnage updates, for many substances the tonnage information has not been revised for a long time and is now outdated. Due to a lack of a ‘coordinated and regular’ updating, no meaningful time trends on the consumption and use volumes can be derived from the registration database.

Therefore, Option 2 suggests that not only more detailed tonnage information is provided but that it is provided on a regular basis, independent of a specific trigger. Regular updating would support all regulatory processes and enable effective monitoring of regulatory impact. Similarly, the ARN would benefit from regular updates for priority setting and the selection of appropriate regulatory instruments.

The updating of registration dossiers could be implemented as a stand-alone measure or in combination with the other options. The selected updating frequency affects the costs and benefits of the first and second option.

**5.3.3 Option 3: New requirements for DUs to regularly report use and exposure information to the authorities**

The third option proposes to establish a requirement for DUs to report the use of certain substances to ECHA as identified to them in the Safety Data Sheet (SDS). The core option focuses on the reporting of the use of Candidate List substances in mixtures and articles, either under the current approach to Candidate Listing or for substances of concern under GRA. The scope of the reporting would include basic information about the notifier, PCs or ACs in which the substance is used, categorisation of use (professional, consumer, industrial), sectors of end-use and concentration ranges and tonnages.

A direct reporting to ECHA appears more feasible and realistic than improved information provision via upstream communication and through the registrants (please note that this option does not intend to replace current upstream communication requirements). The reporting obligation could either be implemented as an extension of the existing reporting obligations or as an entirely new obligation.

**5.3.4 Option 4: New requirement for registrants and downstream users to provide information prior to potential regulatory action**

This option focuses on ensuring that the authorities have up-to-date information for substances that may be subject to regulatory action - this option focuses on one-off provision of information for substances that are candidates for regulatory action. Option 4 comprises two elements:

- registrants updating their (full) registration dossiers upon request of the authorities that are considering implementing a particular regulatory process, such as a restriction. This is illustrated by the example of the inclusion of a substance in the Candidate List.

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33 Under the US Toxic Substances Control Act, a reporting scheme exists requiring all manufacturers and importers to report their annual production volumes every four years.
• downstream users providing the same information that would be provided under Option 3 but only for candidates for regulatory action (inclusion of a substance on the Candidate List).
6 Detailed description of the options for the IA

6.1 Detailed description of the policy options

6.1.1 Option 1: Technical optimisation

Revision of guidance: Clarification of the term ‘professional use’

- Improvement target: Increase reliability and consistency of information on lifecycle stages (LCS)
- Action: ECHA updates guidance documents to ensure ‘professional use’ is unambiguously defined
- Benefits: More certainty about relevance of professional use in ARN and restriction processes, potentially including the potential future GRA restrictions (Generic Risk management Approach)
- Cons: Potential costs for registrants and ECHA

Revision of guidance: Clarification of the term ‘transformation product’

- Improvement target: Support the provision of reliable information on transformation products (including nanoforms), prevent ‘false positive’ flags due to a confusion with ‘degradation products’
- Action: ECHA updates guidance and provides a definition of the term (with a clear differentiation to degradation products) and explains why information is needed. A respective IUCLID field and ‘help function’ is implemented.
- Benefits: Registrants are more aware of and better understand the need to provide information on the transformation. Authorities get more reliable information about the relevance of LCSs
- Cons: Potential costs for registrants and ECHA

Revision of guidance: Updating of use descriptors

The Product Category (PC) use descriptors are crucial for understanding the market for a substance, priority setting and obtaining indicative exposure potentials as well as structuring restriction proposals. In addition, the (granularity of) PCs may influence the granularity of tonnage reporting and has an impact on the supply chain communication (do DUs recognise which ESs address their use, how ‘broad’ could a use advised against be defined etc.). Due to the many uses of the PC use descriptors (with partly different purposes), it is of high importance that the use descriptor system is consistent, understandable and able to accommodate different demands regarding the granularity of PCs. It is therefore suggested to assess, if a hierarchical system could be developed, similar to that implemented in the ACs, which would allow e.g. to use broader PCs for tonnage reporting, for which the registrants would have access to information, and to have a set of very specific PCs grouped under a broader category, which would support the scoping, risk assessment and impact assessment in a (specific) restriction proposal. The development of such a system requires a detailed review of the PC system, comparison with other existing systems as well as consultation with the relevant industries, which is out of the scope of this study. Therefore, only examples of potential options for improving the use descriptor system can be provided here.

34 Alternatively, or in addition, a definition could be included under REACH Article 3.
35 Exposure scenarios
• Improvement target: increase reliability, consistency, completeness, and granularity of information on uses
• Action: ECHA updates the R12 guidance based on an assessment of needs and options (potentially requiring a project to develop proposals) and revises the use descriptors:
  o PC: consolidation considering use of terminology in industry, deleting ambiguous, very broad or very narrow PCs, potentially development of sub-categories or high-level groups of PCs
  o TF: consolidation of use descriptors by removing superfluous and adding missing entries, alignment with industry terminology
  o PROC: inclusion of (better) explanation on which Process Categories (PROCs) apply to which processes to improve consistency in how the use descriptors are applied,
  o ERC: assessment of the possibilities / needs to further differentiate the Environmental Release Categories (ERCs) according to emission drivers and potentials
  o AC: review if Article Categories (ACs) could better reflect exposure potentials and / or legal coverage, as well as industry terminology used in e.g. production statistics.
• Benefit: more certainty for registrants and authorities that the use descriptors are correctly applied; improved differentiation between uses due to clearer structure of use descriptors, lower workload for the authorities to understand the uses of substances and to eliminated inconsistencies and/or cover uncertainties by assumptions.
• Cons: May trigger extensive revisions of existing Exposure Scenarios (ESs) and tools in ECHA and industry and need for upstream communication, especially for refined ACs; requires new or updated exposure assessment tools, since Tier 1 exposure assessments are based on defined exposure levels for current use descriptors.

Revision of IUCLID: Add data fields and make (additional) data fields subject to the TCC (technical compliance check)

The information to describe a use is defined in REACH Annex VI. However, the wording of Annex VI may be subject to interpretation as it is not very specific. The addition of data fields may require a concretisation of Annex VI to ensure this is fully backed by the legal provisions.

• Improvement target: obtain all information from the registrants that is legally required according to Annex VI in a structured form and accessible for automatised processing in IUCLID
• Action:
  o Add a data field: ‘Intended transformation along the lifecycle’ (Yes/No). If registrants tick ‘yes’: obligatory specification at which Lifecycle Stage (LCS) the transformation occurs and whether the transformation product may be (more) hazardous or not.
  o Make subject to TCC: PCs for industrial and professional use
  o Add data fields: make the specification of exposure determinants during use (workers, consumers, and environment) and from article service life obligatory suggesting possible items in picklists such as concentration in the mixture, operating temperature, abrasive conditions.
• Benefits: Authorities get information if a transformation is intended, and which PCs are relevant in industrial and professional uses. Additional information on exposure drivers is provided, more certainty about relevant LCSs and exposure potentials reducing the authorities’ efforts to gather information to close information gaps

36 For example, the PC32 ‘Polymer preparations and compounds’ would benefit from the development of sub-categories for the main types of polymers that, in combination with the TF of a substance would support understanding the emission potential from matrices. Similarly, the PC 1 ‘Adhesives, sealants’ covers a large number of products and sub-categories would support the understanding of the exposure relevance of a use described by this PC.
• Cons: Additional efforts from the registrants

**Specify CSR information: Further differentiating the life cycle tree**

A core information need consists of a clear allocation of the technical function of a substance to a PC and/or AC. At present, the uses in the Chemical Safety Report (CSR) may include one or several PCs/ACs and may or may not list one or several TFs. Therefore, as soon as a substance has more than one function and more than one PC/AC is covered by a use in the CSR, the relation between these use descriptors is unclear.

• Improvement target: Increase the understanding of which function a substance fulfils in a PC or AC.
• Action: Chesar and IUCLID are amended so that registrants are enabled and required to assign a technical function to each PC they specify in the CSR. Per use, PCs may be grouped if the substance fulfils the same (intended) function, i.e. it is possible to assess uses with several PCs but only one TF. The provision of this information is obligatory. Additionally, registrants are enabled (but not required) to provide a TF also per AC in the use description.
• Benefits: the authorities get a better understanding of the links between PCs and TFs and the information is accessible for processing in the registration data base. The CSR does not have to be changed. Requiring specification of the TF per PC may result in a ‘cleaning up’ of uses that are not relevant.
• Cons: additional workload for registrants, TF may not always be known to the registrants

**Import CSR information to IUCLID: Making CSR information available**

• Improvement target: Make (all) relevant information from the CSR available in IUCLID to increase accessibility of data to the authorities
• Action: Make the use of the Chesar format obligatory and/or require all use information in the CSR to be provided in IUCLID, i.e. complete use description including TF, PC, AC, PROC, ERC (and potentially Sector of Use, SU), use tonnages (from environmental assessments), emitted amounts, relevant exposure proxies as identified in the ES. Maintain confidentiality by not displaying sensitive information in the disseminated dossier.
• Benefits: No additional efforts for the registrants (except if Chesar is not used) for future dossiers, all relevant information from the CSR is available in a processable form supporting the assessment of regulatory needs and serving as a basis for restriction proposals
• Cons: information in the CSR is not considered sufficiently reliable; workload required for registrants to revise dossiers already submitted.

**Consistency checks**

• Improvement target: increase completeness and consistency of information within registration dossiers
• Action: Include consistency checks in IUCLID that address the combination(s) of LCSs and PCs/ACs as well as PROCs and ERCs, that address the reported tonnages (total production volume, amounts entered in ESs for environmental assessment etc.).
• Benefits: registrants are made aware of inconsistencies and can improve, less work for authorities to resolve unclear information on the use pattern
• Cons: None identified
6.1.2 Option 2: Additional registration requirements

According to the assessment of information availability, the registrants generally have access to only little more information than they are requested to provide according to the current REACH provisions. It was furthermore concluded that the DUs either may not (legal constraints) or will not (sensitive business information, high workload) provide additional information on the use pattern or tonnages upstream. However, an improvement potential is spotted regarding the tonnage information and the obsolescence of use pattern information in registration dossiers.

Several of the REACH provisions are relevant to the options suggested on tonnage information and updating. The registrants may provide several types of tonnage information in their registration dossiers. The following list summaries which information may or must be provided:

- **Obligatory:**
  - Tonnage band of their own manufacture or import
  - Total manufactured / imported tonnage (as such and in mixtures)

- **Not explicitly required but necessary:**
  - Tonnage per use as starting point for the environmental exposure assessment (and implicitly also for other assessments)
  - Tonnage per local (industrial) site for the local environmental exposure assessment (and implicitly also for other assessments)

- **Voluntary**
  - Manufacturers: total directly exported amounts (voluntary), tonnage applied in the own use and tonnage used by the registrant or a DU as an intermediate under strictly controlled conditions
  - Cumulative tonnage per user group (industrial, professional, consumer)

There is no requirement to regularly update any of the tonnage information, however content-related updating triggers are included in REACH Art. 22 and the implementing regulation on dossier updates\(^\text{37}\) which are relevant for use and exposure information. These are:

- Change of tonnage band (Art. 22(1)c)
- New uses are identified and/or advised against (Art. 22(1)d)
- Updates of the CSR due to new information on risks (Art. 22(1)e)
- Changes in the CSR or information according to Annex VI Section 5 (information on safe use) (Art. 22(1)g)
- Updates due to Commission decisions on restrictions or authorisations (Art. 22(2))

Each dossier update triggers a full TCC, which means that any update might require updating also of other sections if there have been changes to the TCC scope and/or the structure of IUCLID which are not compatible with the current registration dossier.

**Consumption volumes**

- Improvement target: get a better understanding of the consumption volume in the EU and the tonnage split of a substance per LCS and PC
- Action: Include an explicit requirement in REACH (Annex VI) to provide information on
  - The tonnage immediately exported by the registrant

Uses & exposures

- The tonnage used as intermediate
- The fraction(s) of the use volume (potentially ranges) applied per (groups of) uses adding up to as a minimum 90% of the consumption tonnage. The reporting could be related to:
  - industrial, professional and consumer uses, as well as specifying the fraction entering service life
  - groups of uses indicated by broader PCs for which registrants are likely to have tonnage-related information (cf. Section 6.1)
  - specific PCs (not suggested as a part of the option for impact assessment as registrants do not have this information).
- Benefit: Prioritisation is supported by better data on consumption volumes and a more realistic tonnage breakdown than currently available from the environmental exposure assessment. This means the use fractions of the consumption volume would be indicative and based on the registrants’ business statistics and their ‘realistic estimates’
- Cons: Registrants have little information on the volumes used downstream and may only be able to estimate that information

Regular dossier updates regarding tonnages

- Improvement target: Ensuring that tonnage information on the annual consumption and the tonnage breakdown per (groups of) uses in the registration dossiers is up-to-date (at the time of implementing a step in the regulatory risk management, including the ARN), independent of whether tonnage bands change for the registrant
- Action: Change of the REACH enacting terms to implement a requirement to regularly update registration dossiers with regard to the use volumes unless changes are ‘negligible’. Criteria for negligibility have to be defined where no updating would be required
- Benefit: consumption volumes and tonnage breakdowns per (groups of) uses are available for ARN and prioritisation for regulatory risk management, time trends are available to monitor policy impacts of regulations (and differentiate these from already ongoing market trends before the regulatory measure was implemented)
- Cons: Registrants have limited information about downstream uses.

Options for the updating frequency:

a) Regularly, e.g.:
   - every year
   - every 2 years
   - every 5 years

6.1.3 Option 3: Downstream user use reporting

Under the current REACH provisions, downstream users have the following obligations to report use and exposure information to ECHA:

- Content of a candidate list substance in produced or imported articles if the total tonnage of the SVHC in these articles exceeds 1 t/a and the SVHC is contained in these articles in concentrations above 0.1% w/w, unless it can be demonstrated by the article supplier

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38 In addition, information on the identified uses, uses advised against and changes in use due to potential authorisation or restriction requirements should be up-to-date in registration dossiers. Respective updating requirements exist in REACH Art. 22 and an improved enforcement of these provisions are needed, which is not included as a separate policy option here as this is a MS responsibility.
producer or importer that human and environmental exposure can be excluded under reasonable and foreseeable conditions, including from the waste stage. (Art. 7(2)).

- Use of an authorised substance according to the authorisation conditions has to be notified to ECHA at the latest three months after the receipt of that substance as such or in a mixture (with an authorisation number) Art. 66(1).
- A DU who applies a substance as such or in a mixture outside the CoU communicated to him or in a use that the supplier lists as ‘use advised against’ and choses to make a DU CSR must notify the ECHA thereof. If a DU relies on one of the exemptions for making a DU CSR listed in REACH Art. 37(4)c and f he must also make a notification to ECHA. The notification includes a brief general description of the use according to REACH Annex VI Section 3.5.

In addition to the notification obligations under REACH, article suppliers must notify articles and complex objects containing candidate list SVHCs in concentrations above 0.1% to ECHA’s SCIP database according to Art. 9 of the Waste Framework Directive. Importers and downstream users of mixtures that are placed on the market and are classified due the their health or physical hazards shall notify information on, for example, the classification and the composition of the mixture via the Poison Centre Notification (PCN) system.

The suggested improvement option consists of an obligation for DUs to regularly report use and tonnage information directly to ECHA. The DU use reporting is independent of the identification of uses in the registration dossier.

- Improvement target: Gather reliable and granular information on the use pattern of a substance, including tonnages.
- Action: Require DUs to report their use of a hazardous substance to ECHA.
- Benefits: specific information on the use pattern of substances is generated, including tonnages; the authorities gather information on companies and uses of substances for that can be used for market surveillance, enforcement, any regulatory risk management processes, and the authorities have an overview of the relevant market actors.
- Cons: challenging to enforce the implementation of the reporting duty due to a high number of companies and substances, reporting may be unequal across DUs, as the self-classifications may differ per supplier.

Tiered implementation options:

**Basic requirement:** Formulators of mixtures, importers of mixtures, and distributors notify all relevant substances in mixtures. Article producers notify the relevant substances/mixtures used in the production of the articles. Article assemblers and importers do not report, unless they use mixtures for the assembly. End users that are not article producers (service providers, construction sector) do not report. A further differentiation could include the reporting for a wider range of substances, e.g. Candidate List substances under the current approach, substances of concern under GRA or all substances with a hazard classification.

**Companies that have to report**

Further tiering could be introduced by limiting the reporting obligations to certain tonnage thresholds, e.g. no reporting would be required for substance uses below a certain threshold. While this seems

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39 Either the total amount of the substance used per year remains under 1 t or the substances is used for product or process oriented research and development.
attractive, the efforts for checking tonnage thresholds may be higher than just making a notification, in case it is basic and the SDSs are provided in digital format.

Notification content

a) Identification of the notifier
b) Specification of the PCs / ACs the substances are included in
c) Categorisation of users as professional, industrial, consumer
d) Specification of the sectors of end-use for the PCs/ACs produced
e) Concentration (ranges) of the substance in the produced product or article
f) Tonnage (ranges) for the different product types and end-uses.

Periodicity

- Regular reporting: annually, biannually or every five years.

When considering this option, it should be noted that

- Companies should already have a chemicals inventory to implement OSH legislation including all classified input materials and the content of classified substances according to the SDS. Hence, reporting could be based on existing infrastructure in DU companies.
- Reporting of uses in classified mixtures to ECHA is already a requirement under CLP (Poison Centre Notification).
- Reporting of SVHCs in articles to ECHA is already a requirement under the Waste Framework Directive (SCIP).
- Reporting of uses in classified mixtures to national product registries is already required in the Nordic countries.
- There are ongoing discussions about the implementation of electronic SDSs. If these are implemented the reporting would be much facilitated.
- REACH suggests a shared responsibility on the safe use of chemicals. The registration obligation places a large share of that responsibility on the registrants. Up to now, DUs are contributing by implementing the safe CoU but have little reporting obligations. Implementing one would have the advantage of involving them more strongly in the information generation on chemicals, thereby also increasing awareness on chemicals and the (DU) obligations under REACH.

6.1.4 Option 4: New requirement for registrants and downstream users to provide information prior to potential regulatory action (one-off)

This policy option should specifically support the restriction process, but could also be useful for other regulatory measures.

Summary of information needs and availability

Information on the use pattern is needed for developing specific restriction proposals according to REACH Art. 68(1) and to some extent Art. 68(2).

The scoping of the restriction proposal may make use of the registration information but is likely to be already complemented with data from additional information sources. The authorities need up-to-date use data for the scoping of restriction proposals.
A regular update of the registration dossier is already addressed under Option 2. Regular provision of information from downstream users to ECHA is addressed under Option 3. This option focuses on ensuring that the authorities have up-to-date information for substances that may be subject to regulatory action - this option focuses on one-off provision of information for substances that are candidates for regulatory action. Option 4 comprises two elements:

- registrants updating their (full) registration dossiers upon request of the authorities that are considering implementing a particular regulatory process, such as a restriction. This is illustrated on the example of the inclusion of a substance on the Candidate List.
- downstream users providing the same information that would be provided under Option 3 but only for candidates for regulatory action.

**Summary of improvement targets**

- Ensure up-to-date information is available before the start of the regulatory process (one-off update).
- Improvement target: Ensuring that all information in the registration dossiers for one substance are up-to-date before starting the implementation of a regulatory measure. Ensure that there are up-to-date and comprehensive data on downstream use before the regulatory process starts.
- Action: Implement a requirement to update registration dossiers when substances are included on the Candidate List (although it is recognised that dossiers should always be compliant). Change of the REACH enacting terms to ensure that downstream users provide use information when substances are included on the Candidate List.
- Benefit: authorities can start their work based on the most recent information on uses and exposures from the registrants and their downstream users.
- Cons: Downstream users are required to provide information on their uses upon inclusion of the substance on the candidate list.

**6.1.5 Additional recommendations**

It is important to note that the policy options may have to be reviewed in the light of the other foreseen changes of the REACH regulation, because these may change both the anticipated information needs as well as the information availability in the future. Consequently, this may change the relevance of (some of) the options in the overall regulatory risk management under REACH.

The study shows that the role of the product categories is crucial for understanding markets identifying regulatory needs and targeting and implementing regulatory measures. Therefore, it is recommended to dedicate a separate study to the revision of the use descriptor system and in particular the PCs to develop a consistent, potentially hierarchical system of PCs that is able to support all relevant needs.

The updating of registration dossiers is another crucial issue identified in the assessment, as the authorities frequently (have to) base their assessments on outdated information. There are several updating triggers which appear not to be properly implemented. However, the effect of the implementing regulation, which clarified the registrants’ obligations cannot yet be fully judged. Options to enforce dossier updates regarding use and exposure information should be developed at MS level.

Based on the assessment of information needs, information gaps as well as the discussions with the RiME+ members and ECHA, some additional aspects were identified for further consideration that cannot be addressed under this project regarding the interplay between REACH and other legislation:
The information generated under REACH and other policies is currently not used in an optimal way thus missing possibilities for synergies. For example, the information collected under the Industrial Emissions Directive is not easily accessible for risk assessment to the authorities under REACH. Similarly, a standardised documenting and reporting of data from workplace exposure measurements does not exist, which could be used to support decision making on the need and most appropriate risk management instrument to address potential risks to workers. These aspects may fall into the scope of other legislative initiatives that are outside the scope of this study. Vice versa, information from the REACH registration database is not sufficiently evaluated and used by the enforcement authorities to ensure that emissions are prevented and/or reported. The exposure assessment information could be used to improve the BREF documents that define best practice in industrial installations.

Consequently, further efforts are needed to integrate and/or connect the information inputs and outputs across different pieces of legislation to make best use of available data. This may include the development of data standards for reporting exposure information together with the Conditions of Use (CoU).
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Annex 1  Relevant Regulatory Processes and Generic Needs

In the following sections, the results of the information gap assessment are included. Information needs are differentiated into:

- Information on the use pattern
- Information on tonnages
- Information on CoU
- Information on emissions
- Information on exposures

For each of these areas, the specific information needs are introduced with an explanation for which process they are used and why (section “needs”). This is followed by a discussion of information availability considering a) the legal requirements, b) the availability in IUCLID and CHESAR c) the availability of information in the supply chain and d) the availability in other information sources. The assessment of which information DUs have is limited to that information which is not available to the registrant or is not reliable (i.e. default values). A supply chain figure illustrates the information availability. Obviously, information availability varies with the type and uses of a substance and hence, the presented information can only be general indications that will be deepened in the development of policy options.

The assessment focusses on substances registered according to REACH Art. 10 (unless indicated otherwise), because substances registered only as intermediates under REACH Art. 17/18 are generally not prioritised for regulatory measures. Furthermore, substances in the 1-10 t/a band do not require a detailed exposure assessment, i.e. most of the information types discussed in the section on availability are not available for low volume substances. Increasing the information requirements on low volume substances is not considered in this study.

The section ‘overview of consequences’ describes how a lack of information would negatively affect the regulatory process. In general, the following types of negative consequences could emerge from a lack of use and exposure information:

a) Underestimating or overlooking risks and hence, failure to fulfil the core aim of REACH to ensure a high level of protection of human health, as a substance is not subjected to a regulatory procedure
b) Overestimating risks of substances, resulting in spending resources in designing regulatory measures with low added values (i.e. no or low risk reduction) and potentially high implementation costs
c) overestimating risks compared to other substances resulting in an inappropriate prioritisation of substances and a delay in managing the relevant risks
d) failing to identify the most suitable regulatory option, which may have different consequences, e.g.
   a. failure to protect human health and the environment due to overlooking risks,
   b. triggering regrettable substitution due to uncertainties in the ability of market actors to substitute
   c. double regulation and/or inconsistent legislation due to a lack of knowledge on the existence of other legislation
   d. waste of resources because a regulation only covers some of the relevant risks and others must be addressed with an additional measure (e.g. authorisation and restriction according to REACH Art. 69)
e. waste of resource, e.g. if authorisation is selected and market actors submit many AfAs that must be processed but not triggering substitution
e) failing to demonstrate a risk when drafting restriction proposals due to lack of supportive evidence, resulting in a waste of resources and potentially the continuation of problematic uses
f) covering uses unknown to the regulators by a measure that should not have been covered (no risks, no appropriate reactions of the market actors possible etc.) resulting in unintended market impact with low added value
g) failure to create regulatory pressure to substitution where it is possible or addition disproportionate regulatory pressure on the market, where a use is considered essential
h) inability to monitor if a regulatory measure achieves the intended goals
i) lack of specific knowledge on the market effects of regulation to adapt a regulatory measure according to a monitored impact

Each section is ended with an initial evaluation of the relevance of the information gap and a list of policy options which will feed into the development of policy options in the next step.

**A1.1 Assessment of regulatory needs**

In the context of the integrated regulatory strategy, ECHA analyses information on all registered substances to assign them into one of the five substance pools, of which the two listed below are relevant for the current study. A hypothesis on the hazard of substances is built based on the registration data and by forming substance groups. Use and exposure information is needed to decide whether a substance can be deprioritised (low hazard and/or low exposure) or should at enter a next step. Hence, based on the ‘likely hazard’ and use and exposure information, the substances are considered as

a) currently not requiring further risk management at EU level, i.e. based on the available information it is NOT a candidate for regulation or
b) requiring further regulation at EU level, with an indication of what type of measure this should be

‘Further risk management at EU level’ may mean (as a first step) to generate further information about the substance’s hazard, e.g. to verify the conclusions on hazards derived from grouping, because use and exposure information suggests that data waiving is not justified, or because hazard data relates to irrelevant exposure routes and therefore, a dossier or substance evaluation is needed. The information needs on use and exposure to facilitate the decisions about data generation are not subject to this study.

The holistic assessment of hazard, use and exposure information in the registration dossiers results in a recommendation of what regulatory instrument would be most appropriate to address potential risks. The regulatory instruments that could be selected include:

- Harmonised classification and labelling
- Identification of SVHCs with subsequent Authorisation
- Restriction
- Developing harmonised Occupational Exposure Limit Values (OELs)
- Risk management under ‘other legislation’

Which of the regulatory instruments are selected depends partly on the substance hazard (i.e. SVHC identification is only possible for substances with respective properties), but is mainly driven by use and exposure information in the registration dossiers. For example, knowledge on the (volume of a
substance entering) specific uses can indicate if (these amounts) are covered by other legislation and/or exempted from certain REACH provisions, and hence the respective processes not feasible. An overview of the use pattern indicates the main concerns, i.e. whether a substance is used in consumer mixtures, if the inclusion in articles potentially causes high environmental emissions from diffuse sources, or if workers in industrial sites are the main group of exposed persons.

The restriction process and the authorisation process under REACH are currently under revision. At present, the REACH text defines various types of restrictions: Restrictions according to:

- Art. 68(1) require demonstration of risk that needs addressing at Community level and a socio-economic analysis (SEA) demonstrating the proportionality and/or overall benefit of a restriction. Hence, detailed information on uses is needed as well as on the affected market sectors and products to scope and justify a restriction.
- Art. 68(2): which corresponds to the Generic Risk management Approach (GRA). This approach will be extended according to the Chemical Strategy for Sustainability regarding the scope of hazardous properties and potentially also by including professional uses. The application of this approach requires some information about the uses of substances to justify a restriction is needed, but neither demonstration of risk, nor a SEA are needed.174
- Art. 69(2): can be applied for SVHCs on the authorisation list if ECHA identifies the use of the SVHC in articles as relevant and potentially causing risks. Consequently, information on the article uses and related exposures are necessary.
- Annex XVI, Entries 28-30 specifies that the placing on the market of CMRs Cat. 1A/B included in Annex VI of the CLP regulation (table 3.1) is restricted for any consumer uses as such or in mixtures above the specified concentration limits. Here, a harmonised classification ‘quasi automatically’ triggers a restriction

In the assessment of information needs and information gaps, we assume all the above types of processes will remain in place in the future, with the number of substances being restricted under Art. 68(2) (GRA) increasing and those under Art. 68(1) decreasing, accordingly.

The assessment of regulatory needs is implemented by ECHA in the scope of the Integrated Regulatory Strategy as well as by the MSs Competent Authorities (MS CAs). The assessment of regulatory needs by the MS CAs draws upon the registration information but also considers additional information sources and (national) priorities, such as evidence from the occupational area or environmental monitoring.

**A1.2 Drafting Restriction Proposals**

Restriction proposals may be drafted by ECHA (on request of the Commission) or by the MSs. As the granularity of information on uses and exposures needed to demonstrate a risk, target the restriction proposal, and develop a SEA, the registration data is usually not sufficient to compile an Annex XV dossier. Additional information sources are needed and uses, such as the SCIP database, information from statistics and industry associations and from consultation. A restriction proposal may be developed following:

- Art. 68(1): a full Annex XV dossier must be compiled to demonstrate that a risk is not adequately controlled and/or that the emissions of non-threshold substances are not

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174 In practice the generic restrictions for placing on the market CMRs Cat 1A/B as such or in mixtures for consumer use (Annex XVII, entries 28-30) are proposed without knowledge about uses. For the restrictions of CMRs in consumer articles information on uses (in articles) was essential.
minimised by the operational conditions and RMMs implemented in the market. In addition, an assessment of alternatives and a socio-economic analysis are required.

- Art. 68(2): the Generic Risk management Approach does not require demonstration of risk or socio-economic impacts. It is currently unclear how the process will be implemented in practice, but the further extension of the shifted burden of proof will remain the core characteristic of the approach, thus making information collection on detailed information uses and exposure superfluous for the authorities.\textsuperscript{175}

- Art. 69(2): use and exposure information are needed to check whether a restriction complementing the existing authorisation requirement is justified, i.e. if a substance is used in articles at all and if these uses could cause risks. If a restriction need is identified, the restriction proposal would follow either of the above two routes.

The information needs for drafting restriction proposals generally include use, emission (non-threshold substances) and exposure information to demonstrate risks are not adequately controlled or emissions are not minimised. The level of granularity must be sufficient to develop reliable risk assessments. Socio-economic data, in this context information on the uses, use sectors and relevant products are needed to identify the benefits and costs of a restriction. Which information is exactly needed depends on the restriction route, the hazard of a substance and the intended restriction scope.

### A1.3 Prioritisation for Authorisation

ECHA develops recommendations about which SVHCs on the candidate list should be included in the authorisation list with high priority. As SVHCs are generally earmarked for regulation, use and exposure information is mainly necessary to determine the urgency with which they should be authorised. In this regard, the information used for all SVHCs should be comparable and the decision making predictable, to support the market actors’ adaptation to regulation.

The process of deriving recommendations for including substances in Annex XIV has been described by ECHA\textsuperscript{176} and is based on three criteria (REACH Art. 58.3), of which one is hazard based. According to ECHA’s scoring system, use and exposure information needs concern:

- The registration volume within the scope of authorisation (i.e. the volume for intermediate uses is subtracted)
- The use pattern of a substance and the related exposure potential (wide dispersive uses) indicated by the existence of industrial, professional and consumer uses

Additional information may be used to refine the scores or consider further aspects in the prioritisation, such as the interchangeability of substances in their uses, which is indicated by an evaluation of the technical function of a substance, structural similarities, and the reported uses. In addition, ongoing risk management activities under REACH, CLP or under other legislation may be information that is used in the prioritisation. Finally, information on presence of the substance in articles and the related tonnage for that use may be used to refine the scoring of wide dispersive uses. For the latter, indications of the release potential of SVHCs from articles may also be used.

\textsuperscript{175} Under the CSS the concept of essential uses may be introduced potentially as an option to assess whether exemptions from the scope of a restriction are justified. However, the needed detailed information of the use is expected to be provided by the market actors asking for an exemption.

\textsuperscript{176} ECHA (2014): Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)
**A1.4 Assessment of Applications for Authorisation**

Authorisation applications are provided by the industry actors. The RAC forms an opinion on the chemical safety assessment provided and the SEAC assesses the applicant’s SEA and analysis of alternatives. Although AFAs should include sufficient information for the committees to assess them and form their opinion, the published opinions by both committees show that this is frequently not the case, i.e. the authorities either collect additional information or take decisions despite (relevant) information gaps.

In this study, all information needs of the authorities to challenge the applicants’ risk assessments and risk conclusions are not further discussed. As the authorities can ask the applicants to provide missing information and the applicant can cooperate with their DUs in this regard, no need for policy options to gather further information exists.

**A1.5 Monitoring Policy Success**

Monitoring the impacts of regulatory activities generally requires data before and after a regulatory action to identify any changes in the use of a substance and of substances that may act as substitutes. A comparison of the use pattern and use amounts would give already a first indication of changes in the market that could be attributed to the regulatory action. To exclude other factors influencing the markets and potentially changing the use and exposure patterns, longer time trends for substances of concern would be necessary, including to identify potential shifts in risk and/or regrettable substitution. Depending on the type of regulatory measure and its objective, also information on the actual release of substances or exposure levels (at the workplace) may be necessary. The information needs generally concern time trend analyses about:

- The use pattern of a substance and the volumes entering specific uses
- The exposure levels of humans and the environment and/or the health and environmental quality that may be affected by the hazardous properties of the substances
- An indicative number of workers exposed
- Overall changes in the market of the products affected by a regulatory action
Annex 2  Identification of information needs and gaps

A2.1 Information Needs on the Use Pattern

The information on the use pattern should give an overview of the various use types of a substance. This would result in knowledge of

- Whether the use is widespread, i.e. the user groups (industrial, professional, consumer) and whether a service life exists
- within which product types (product categories and article categories) and in which sectors it is used
- which technical function it fulfils and whether it is intended to transform
- whether (some of the) uses are covered by existing legislation and/or cannot be covered by some of the REACH risk management instruments

A2.1.1 Lifecycle stages

The information needs for the assessment of regulatory needs including recommending SVHCs for Annex XIV inclusion, drafting restriction proposals and monitoring policy success are provided in the following table.

Generic information on the life cycle and uses of substances is most needed at the beginning of the regulatory process as it serves as a proxy for the diversity of uses and the exposure potential. Hence, this information facilitates the identification of regulatory candidates and gives an indication of the type of measure that could be appropriate to address potential risks. While the information can be used for drafting restriction proposals as a starting point, more detailed data are needed for demonstrating risks or making SEAs. The assessment of regulatory impacts would benefit from this information, if available as time trends.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of Regulatory Needs</th>
<th>Restrictions</th>
<th>Measure policy impact</th>
</tr>
</thead>
</table>
| Relevant life cycle stages (LCS) | Identify exposure potential / get indication of risk
Identify wide dispersiveness of use, how many and which user groups could be exposed and whether they have capacities to manage risks
Identify if service life is relevant
**Decision on regulatory instrument**
Lack of article service life could indicate to authorisation as appropriate
Use in consumer mixtures may suggest CLH to trigger restriction in REACH Annex XVII as relevant
Only industrial use points to options strengthening OSH or environmental legislation, e.g. via CLH or OELs | **Scoping proposal**
Identification of relevant life cycle stages | **Changes of in the market**
Time trends on use by industrial, professional or consumer uses to monitor changes in the market |

A2.1.2 Product and article categories

Information describing the products in which a substance is used via the standardised use descriptors PC and AC or via the name of a use are important exposure proxies of a substance’s use and hence relevant for the identification of regulatory candidates and the identification of an appropriate regulatory measure. The more detailed this information is the better is the exposure proxy and hence the authorities’ judgement on the regulatory need. Information on PCs and ACs are also needed as a
basis for scoping and justifying restriction proposals and structuring both the risk assessment and the SEA. Time trends on PCs and ACs are important indicators of policy impacts on the market.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Measure policy impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information on relevant products (PCs/ACs of R12 guidance)</td>
<td>Identify exposure potential / get indication of risk Exposure proxy Identify (potential) regulatory coverage Existence of product legislation (e.g. cosmetics, vehicles) Applicability of regulatory instruments (authorisation, generic restrictions etc.) Decision on regulatory instrument Identification of (the number of) PCs/ACs with higher risk potential that can be addressed</td>
<td>Scoping proposal Identification of mixtures that could/should be addressed by a (generic) restriction Identification and structuring uses that could be restricted Risk assessment PCs/ACs are needed to structure the risk assessment. For generic restrictions this may be sufficient, for specific restrictions more detailed information is need, also to identify impacts on the market</td>
<td>Changes of in the market Time trends on use in products informs about which impacts a regulatory measure has on the composition of products and related exposures</td>
</tr>
<tr>
<td>Exposure proxies for articles</td>
<td>Identify exposure potential / get indication of risk Differentiate articles with low from those with high release potential</td>
<td>Prioritisation Prioritise relevant articles in generic restriction proposals Scoping proposal Include or exclude articles according to exposure potential / relevance Risk assessment High granularity needed to identify risks from articles SEA High granularity needed to identify potential benefits from reduced exposure</td>
<td>Not relevant</td>
</tr>
</tbody>
</table>

### A2.1.3 Sector of use

Information on the affected sectors is useful to identify appropriate regulatory measures and to structure a SEA. For monitoring regulatory impacts, time trends of that information would be useful. No strong need for improved information was observed, however.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Measure policy impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affected sectors (SUs according to R12 guidance)</td>
<td>Decision on regulatory instrument Type of affected sectors may indicate market impacts of measures</td>
<td>Scoping proposal Indication of risk management capacity of the actors and/or relevance of uses Indication of how to get access to actors SEA Indication of what specific sectors (and their uses) could be affected (addressing the right actors in consultations)</td>
<td>Changes of in the market Time trends on use sectors informs about how sectors react to a measure</td>
</tr>
</tbody>
</table>
A2.1.4 Information on the number of sites applying a substance and workers exposed, information on exposed consumers

If a substance is only used at industrial sites, the identification if that substance is a priority for regulation is supported by data on the number of sites (widespread use) and exposed workers (exposure proxy). If this indicates a potential risk, this information will also support the selection of an appropriate regulatory measure. If a restriction proposal is drafted, this data is necessary input information to the risk assessment. Time trends might be needed to measure policy success of measures taken.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Measure policy impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of industrial sites applying substance and exposed workers</td>
<td>Exposure potential / get indication of risk Exposure proxies Decision on regulatory instrument Indication if CLH and OSH legislation and/or emission controls under IED could be sufficient Indication of potential scope of a restriction or that authorisation may be a better instrument</td>
<td>Risk assessment Input data to specific risk assessment in the OSH area SEA Indication of benefits and costs</td>
<td>Time trends Only in specific cases</td>
</tr>
<tr>
<td>Number of exposed consumers</td>
<td>Exposure potential / indication of risk Exposure proxy Decision on regulatory instrument Indication if CLH and generic restriction for mixtures could be sufficient</td>
<td>Risk assessment Input to specific risk assessment SEA Indication of benefits and costs</td>
<td>Time trends Monitoring reduced exposure</td>
</tr>
</tbody>
</table>

Availability of Information

Legal requirements

REACH Annex VI (point 3.5) requires a ‘brief general description of the identified use(s)’, which according to the R.12 Guidance (ECHA, 2015), ‘applies to normal registration (Article 6), registration of intermediates under strictly controlled conditions (Articles 17(2)(e) or 18(2)(e)) or registration of substances in articles (Article 7(1) or (5)). It does not depend on whether a chemical safety assessment has to be performed, or the volume of the use where the substance is supplied at. It applies to all types of substances (classified/non-classified) and all tonnage bands (including 1-10 t/y)’. REACH Art. 10 is more explicit and requires registrants to submit for registration required by Article 6 or by Article 7(1) or (5) (emphasis added) ‘information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant’s identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories’.

REACH Annex VI (section 3.5) only requires ‘a brief general description of use’, while REACH Annex VI (section 6.1) requires information on the main use category (industrial, professional, consumer) for substances registered at 1-10 t/and therefore appears more explicit than the general registration requirements. Overall, REACH does not explicitly refer to use descriptor terminology (including life cycle stages) as applied in the R.12 Guidance (ECHA, 2015) and in IUCLID and does not even require the use of ‘use categories’. However, the use of IUCLID is a legal requirement and a registration dossier will not be accepted if the use descriptor system is not used at all.
There are no legal requirements to specify the complexity of the supply chain (per use), identify if articles are only used in industrial users, explicitly mention the sector of use, whether a use is covered by legislation, or provide (an estimate of) the number of user sites and exposed workers.

**Implementation in registrations**

IUCLID basically implements the provisions of the of R.12\(^{177}\) (ECHA, 2015) and requires that the relevant use descriptors (UD) are provided. In fact, the structure of IUCLID (and CHESAR) already implements the life cycle stages (LCS) as separate IUCLID sections (3.5.1-3.5.6) within which ERCs, PROCs, PCs and ACs are specified for each exposure scenario. The specific use descriptor subject to the technical completeness check depends on the LCS (e.g. PROCs need to be provided for industrial and professional uses, while PCs need to be provided for consumer uses). The SU may be provided but is not required and subject to the TCC.

The TCC implemented in IUCLID ensures that UDs are provided as appropriate and in relation to the LCS. For example, at least one ERC (in the section ‘contributing activity / technique for the environment’) and one PC (in the section ‘contributing activity / technique for consumers’) must be included in the registration dossier. In addition, some more validation rules are implemented, for example to ensure that a service life scenario is provided if the other information indicate that this is needed (selection of ERC 5: inclusion of a substance into/onto an article). Consequently, REACH registration dossiers\(^{178}\) typically contain basic information on the use pattern as described by the UD system, allowing to identify and differentiate industrial, professional and consumer uses as well as associated service life scenarios. Furthermore, the name of a use must be provided as it is subject to the TCC. Note, however, that the UD subject to the TCC\(^{179}\) depends on the LCS. For example, a PC is required for consumer uses, but not for professional or industrial uses (for which the PROC is subject to the TCC).

The granularity of the information provided differs in some cases. As shown in the following example, the UD system provides more specific descriptions for articles (AC as well as sub-categories), but not for products (PC only).

**Example: more specific information on products**

The UD list for articles in R.12 (ECHA, 2015) defines sub-categories but the list for products (PCs) are not further differentiated. Consequently, the use description includes article sub-categories (as implemented in CHESAR and – with slightly different wording – in ECETOC TRA) in service-life scenarios but does not differentiate any product sub-categories. However, there are sub-categories for PCs defined in ECETOC TRA and they are also available in CHESAR (as shown here for the sub-category ‘glues, hobby use’, which is a sub-category of PC1 (adhesives, sealants)).

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\(^{177}\) Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12. We simply refer to R.12 (or other chapters of the same Guidance) below for easier readability.  

\(^{178}\) Refers to dossiers submitted after revisions of R.12 and IUCLID/TCC rules in 2015. As noted earlier, we focus here on substances requiring a full registration and a exposure and risk assessment.  

\(^{179}\) Subject to the TCC only means that information is required, but the TCC does not assess the adequacy of the information.
This more detailed PC information is not exported to IUCLID since a corresponding field does not exist. Inclusion of this information in the ‘identified use section’ in IUCLID (based on the same picklists already implemented in CHESAR) would increase the granularity of information on industrial, professional and consumer uses. The suggested addition shown in the following example would not only facilitate automatic screening for specific uses (in glues) but could also serve as an exposure proxy (lower exposure expected for hobby glues than for DIY glues at otherwise identical conditions). Furthermore, such an inclusion of PC sub-categories would provide an indication of the number of different product types potentially on the market (whether a substance is only used in glues for hobby use or also in DIY glues, and sealants). As shown in the following example, it is also independent of the name assigned by registrants (which may be very broad).

This example implements the sub-category as an addition (i.e. specifying PC1) but it would also be possible to include the information in the existing picklist (i.e. PC1 or one of the sub-categories can be selected). The latter approach has the advantages that it is identical to the one already implemented for articles.

The following matrix summarises the IUCLID picklists for one product category (adhesives, sealants) and one article category (plastic articles), highlighting the differences with respect to sub-categories, which can be selected for articles, but not for products.
Sub-categories in ECETOC TRA/CHESAR | Glues, hobby use | Same as above
| Glues DIY-use | Glue from spray | Sealants |

It is also noted more generally that the product categories in the R.15 Guidance (ECHA, 2016a) differ from the ones in the OECD Harmonised Templates (OHT) for consumer uses\(^{180}\). The OHT categories also contain sub-categories that differ from the ones used in ECETOC TRA. However, adoption of the OHT product (sub-)categories is not considered meaningful, since (a) the input data in the consumer model of ECETOC TRA have been developed for the specific sub-categories (which may not exist in the OHT) and (b) this would introduce new (sub-)categories for which no input data are available in ECETOC TRA. This would prevent a tier 1 exposure estimation and necessitate the development of input data for a large number of products\(^{181}\).

Some problems exist in using the information on use patterns in a meaningful way. Each exposure scenario (i.e. each use/service life) may include several contributing activities (each assigned a UD). For example, a very broadly defined consumer use (use name: ‘Consumer uses of the substance’) could – in principle – include contributing activities for all PCs of the UD system. The same is true for service life scenarios involving ACs and/or article sub-categories. While the number of PCs and ACs can still be deduced from data provided in such a way, other information is only provided for the ES, most notably the TF (see section 0), the tonnage used (see section 0) and the SU.

It is also possible in principle to define very broad formulation, professional and industrial scenarios (‘Professional use of the substance’) with inclusion of all PROCs making it impossible to ascertain whether these PROCs relate to all professional uses or are a combination from several professional uses. Furthermore, since the PC is not required for formulation, industrial and professional scenarios, it may remain unclear which kind of products workers actually handle.

A possible solution of these problems consists in defining default use/service life names that must be used. Only a single name could then be selected, and the assigned UD would need to meet consistency requirements. A very simple example would be a standard use name ‘Consumer use of adhesives’ to which only PC 1 can be assigned. While the sheer number of possible combinations, the potentially large number of justified exemptions and the large number of resulting ESs may prevent an implementation, this should not prevent considering such an approach to some extent.

Several information needs are not explicitly included in the dossier, but may be deduced from the information provided:

- The Complexity of supply chains: may be approximated from
  - the types of LCS (only manufacture and industrial uses vs. manufacture, formulation, industrial, professional and consumer uses as well as service life scenarios)
  - the number of entries for each type of LCS (one professional use vs. many professional uses, one service life scenario vs. many service life scenarios)
  - the number of contributing activities per consumer use/service life scenario (only one contributing activity vs. many contributing activities)\(^{182}\)


\(^{181}\) It is also noted that the article categories under REACH are more aligned with the OHT.

\(^{182}\) For example, a service life scenario ‘rubber and plastic articles’ may include only two specific types of articles (such as the two sub-categories ‘large surface area articles’) or all seven rubber and all seven plastic article sub-categories (also see text for discussion of this issue).
the number of different SU assigned to industrial and professional uses (if provided; but also see next bullet point)

- Affected sectors of use/market sectors: SU may be assigned to industrial and professional uses in registration dossiers, but this is not mandatory information. In fact, it is only expected if a substance is used in few SU (ECHA, 2015). CHESAR includes a ‘market’ functionality, but its use is not mandatory, and the information is not exported to IUCLID. The concept of ‘markets’ combines several UD (SU and PC and/or AC, for example adhesives/sealants (PC 1) used in building and construction (SU 19)), but markets as such are not entered in the dossier.
- Articles used only in industrial sites: this information can directly be deduced from the dossier, if only service life scenarios for workers at industrial sites are included.
- Specific information on the number of industrial sites where a substance is used, and the respective number of exposed workers is not provided in the registration dossier. It can also not be deduced from the use descriptions.

The coverage of uses under other legislation may be deduced from the use descriptors, e.g. if the technical function (the specification of which is not obligatory) is ‘biocide’ it is obvious that the substance is covered under the biocidal products regulation. However, in most cases this information cannot be unambiguously deduced from the use descriptions. As a restriction under other legislation than REACH does not trigger an update, the use patterns of substances may include uses that are not relevant or compliant with the existing legislation.

**Availability of information in the supply chain**

The registrants define the uses they intend the substance to be applied in or that they have been made known by a DU and can therefore specify the use name(s) and the relevant life cycle stages. However, DUs may apply the substances for other uses than those identified by the registrants. If the ESs the DU receives covers his uses, there is no action need for the DU. Otherwise, he may communicate uses upstream to have it included in the registration or make a DU CSR. Since the CoU in the ESs are frequently very broad and the ESs are not actually enforced, little upstream communication is triggered.

Formulators making mixtures for an industrial, professional or consumer use that are unknown to the registrant are unlikely to be communicated upstream as this is sensitive market information that is not normally shared. Likewise, the users of mixtures may apply them in different ways than intended by the formulators. The use of a mixture in an article resulting in an (unintended) service life may be known to formulators and is known by the article producer using it. All information on uses may be (considered) confidential and it is unlikely to be communicated upstream unless there are respective legal obligations.

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183 R.12 states: ‘The SU may in particular be specified when a use is specific to one or few sectors. In the case of uses taking place across many sectors, this element may not be needed as registrants are not expected to provide an exhaustive list of all sectors.’
The registrants know the markets for which they produce a substance and are therefore able to generically describe the PCs and, depending on the specificity of a substance, also the material based ACs as well as the SUs that they consider relevant. Hence, a generic use description based on the R.12 SUs, PCs and ACs indicating potential uses is considered available. However, regulatory risk management requires information on the actual uses, which the registrants are not fully aware of due to a lack of respective upstream communication.

Information on the actual PCs and ACs and sectors of use are available along the supply chain as each actor knows his own use and that of the immediate customers. Whether this information can be communicated up the supply chain depends on the innovativeness of the use and the competitiveness of the respective markets. In general, the actors at the end of the supply chain have the most detailed information about the exact use but may not be aware of the content of the substance in their products.

The information on the number of sites applying a substance and the workers potentially exposed to a substance is not available at any of the actors in the supply chain. The registrant may be able to estimate the number of sites for substances which have a very specific use (and potentially short supply chain). The formulators may also have a general estimate of the number of user sites based on their knowledge of the (size of the) user market. This information may be confidential, in particular for specific (non-identified) uses.

The registrants may be able to deduce from the technical function (e.g. biocide) if a substance enters a regulated use or not. In addition, intended uses in mixtures that are regulated are known and the information is accessible to the authorities if the respective TFs or PCs are selected. The formulators have better knowledge of regulated uses in mixtures, specifically for those substances which are no active ingredients, i.e. where the function does not indicate the regulatory status. The formulators
also know if they supply a mixture to producers of articles for which specific legislation exists. While the information on which PC/AC a substance is used may be considered confidential, the fact that a substance is used for a regulated PC/AC could be provided upstream. Mixture users and article producers are also aware of whether their input materials and/or products are regulated.

Figure 5: Availability of additional use information along the supply chain

Additional information on a use

![Diagram showing information flow](image)

Arrows indicate potential information flows upstream, crossed out = 'does not take place', dotted lines light cross = some information flows

**Information in other information sources**

Information on the use pattern of substances at various levels of detail could be obtained from other sources. The following list provides the information source and specifies what information could be obtained, including limitations regarding the scope, reliability, or efforts to use the data for regulatory purposes:

- **SCIP Database**: information on the use of SVHCs in articles from the article supply chain actors. Not relevant before SVHC identification. Other hazardous substances may be reported on a voluntary basis. The level of granularity is higher than ACs. Includes information on the actors producing an article. Completeness of information is unclear as level of compliance is not determined.

- **DU CSR reporting**: DUs not covered by an ES and making a DU CSR notify general information on the use (i.e. LCSs and products used) to ECHA. The number of DU CSRs is low due as the legal trigger is subject to interpretation.

- **Poison centre notifications**: Formulators must report on their mixtures, differentiating for industrial, professional and consumer uses. Product categories are more granular than PCs. Formulators know the end use. Limited to mixtures classified hazardous to health. Data can only be used for poison centres. Information incomplete until 2025, no regular updating.

- **SPIN database**: DUs annually report on product types, and their intended use. Limited to information on Nordic markets.

- **Substances approved for regulated uses (biocides, cosmetics, food contact materials, drinking water contact materials)**: databases allow verification if identified uses exist (biocides only active substances), no systematic updating, partly limited data access for ECHA.

- **Consultations about Annex XIV inclusion**: information on the use pattern (PCs/ACs or as “free text”) may be provided. Limited to SVHCs, information not available for ARN. Representativity unclear.

- **Consultations of restriction proposals**: information on the use pattern may be obtained at higher granularity than PCs/ACs as well as some details on the structure of use sectors and user companies. Information quality and extent varies depending on response rate and outreach to the relevant actors. Only relevant for restrictions.
• Call for evidence (restrictions, OELs): may generate information on the use pattern depending on the questions of the CfE, limited by response rate, representativeness and quality of information unclear.
• Letters according to Art. 36: ECHA / MS may request information from market actors relevant to document compliance with REACH. Information is company specific, cumbersome to get and not easily accessible
• Additional information sources on use pattern information may include websites of companies and associations, scientific literature or commercial market surveys. The evaluation of these sources is cumbersome, and information may be available only for a limited number of substances.
• Active information requests to registrants and/or DUs may be made to obtain additional information on the use pattern. The success of information gathering depends on the willingness of the market actors to contribute.

In summary, there are many information sources that could be consulted to either verify the existence of a life cycle stage, product or article category or legal coverage of a substance. These sources may in exceptional cases be used for the ARN but appear relevant to support drafting restriction proposals. The latter may evaluate information sources first and complement knowledge by specific calls for evidence / consultations with the stakeholders. The monitoring of policy success is not supported by the additional information sources, except market surveys that include time trend data.

**Consequences of current information gaps**

As described above, the generic use pattern of a substance as intended/supported by the registrant is available. However, the degree to which this use pattern corresponds to the actual uses in the market is unclear, as confidentiality concerns as well as a lack of incentives hampers respective upstream communication which might trigger an updating of the registration dossiers.

If reliable information on the actual use pattern in the market, i.e. the PCs and ACs are not available, substances may either be overlooked (failure to ensure high level of protection) or be wrongly prioritised (superfluous measure, inefficient regulation). Lack of information on the legal coverage of uses may have the same consequences, as assumed risks may already be sufficiently addressed under other legislation or assumed to be covered, which is actually not the case.

The selection of an appropriate regulatory impact is hampered by a lack of information on PCs and ACs that are relevant in the market because the authorities cannot properly assess what scope a measure should have, which supply chain actors might be affected and what potential benefits may be generated for which user group. If legislation already covers relevant uses of a substance and this is not known to the authorities, there is a risk of starting a regulatory process that is unnecessary as risks are already addressed.

If substances are used in industrial uses only (mixtures or articles), the selection of regulatory measures may be more flexible, as also other legislation may be appropriate for risk management. Hence, if it is unknown that a substance is exclusive used in industrial settings the selection of the regulatory measure may address too broad a scope / range of uses but be too generic to manage the risks in sites.

If the information on the use pattern of a substances is not up-to-date, i.e. includes non-actual uses and sectors of use, the authorities may unnecessarily spend resources on designing regulatory measures, making risk assessments of non-existing uses or overlook relevant uses that are not obvious from the PCs / ACs. For example, this may result in too broad or too narrow a scope of specific restriction proposals under Art. 68(1). Wrongly targeted regulatory measures might cause additional
(unnecessary) enforcement work or uses might cause damage to health and environment that could be prevented if the use had been known.

In the lack of actual information on relevant SUs, PCs and ACs, authorities may fail to involve the relevant industries in consultations, with an increased likelihood of either unwanted regulation of uses that cannot implement the restriction (yet, e.g. due to lack of alternatives) of interventions late in the process (e.g. when opinions are formed) requesting exemptions from the scope.

If restriction proposals are developed, existing legislation for the uses of a substances will be identified and analysed in detail. Hence, if that information is available at least in parts, this would reduce the resource needs. Similarly, if a restriction is intended for a substance that is exclusively used in industrial installations, information on the number of sites and the number of exposed workers are needed for the SEA. In lack of this information, the authorities will invest resources in researching it.

The prioritisation of SVHCs for inclusion in Annex XIV is based on ECHA’s scoring system. If solid information on the use pattern is missing, i.e. PCs or ACs are assumed relevant which do not exist in the market, a high priority may be given to an SVHC for inclusion in Annex XIV which is not relevant in the market anymore. Vice versa if (wide dispersive) uses of SVHCs are not reflected by the use pattern provided by the registrants, SVHCs may not be included in Annex XIV. In the former case, risk management of other substances which are more problematic may be delayed and SVHCs with uses of low exposure potentials may be regulated. This may result in a high amount of AfAs for that substance (as risk are considered adequately controlled) and potentially significant impacts on the market actors.

To assess the impacts of a regulatory action, the changes in the market over time, i.e. which uses are ended, which new ones are emerging after the regulation, which sectors do or do not stop using a substance etc. are important trend data that help understanding the impacts of a regulation. Depending on the type of measure, the impact assessment may require specific information (including the number of sites using a substance before and after regulation as well as the number of exposed workers) or be based on rather broader uses, e.g. entire sectors phasing out the use of a substance.

### A2.1.5 Technical function

Information on the technical function (TF) of a substance is useful for many regulatory processes as it a) indicates its potential to serve as an alternative and b) as it may allow deducing the relevance of different life cycle stages and the occurrence of transformation products that are due to that intended function. Substances may have one or several functions that each may be relevant either only in one product category (PC) / article category (AC) or in many. Hence, a clear (1:1) relation between TF and the PC/AC may be important for some but not all substances.

**Information Needs**

Information on the technical function as such or in close relation to a PC / AC support the assessment of regulatory needs by informing about the relevance of life cycle stages, potential transformation as well as the interchangeability with other substances. It supports drafting restriction proposals as an input to risk assessments and to the identification of alternatives.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Monitor policy impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical function</td>
<td>Identify exposure potential / get indication of risk</td>
<td>Scoping restriction</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Need for Information</td>
<td>Assessment of regulatory needs</td>
<td>Restrictions</td>
<td>Monitor policy impact</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td>Some technical functions indicate the release potential of a substance and/or whether a substance is transformed or consumed along the life cycle (i.e. not available for the following ones). Some technical functions can also be associated with ‘typical concentrations’</td>
<td>May help defining scope, but usually defined by other parameters</td>
<td>Monitor policy impact</td>
</tr>
<tr>
<td></td>
<td><strong>Identify (potential) regulatory coverage</strong></td>
<td><strong>Risk assessment</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Some substances cannot be regulated under authorisation, some functions indicate existence of other legislation (e.g. active substance)</td>
<td>Potential input parameter determining relevant LCSs (e.g. reactive substances)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Decision on regulatory instrument</strong></td>
<td><strong>SEA</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consistency across legislation through regulation of groups</td>
<td>Supports identification of alternatives</td>
<td></td>
</tr>
</tbody>
</table>

**Availability of the information in registration dossiers**

**Legal requirements**

REACH Annex VI (section 3.5) requires ‘a brief general description of use’ for Article 10 registrations but does not include any explicit reference to the technical function as an item belonging to that use description. The function of a substance is mentioned explicitly only in REACH Article 118.2 b) which specifies that the precise use, function or application of a substance or mixture may be considered confidential information.

**Implementation in registration**

The technical function as such cannot be derived from other information but must be provided as such whereas the function in a mixture or material can at least partly to the extent use descriptors are available and sufficiently specific be deduced from a combination of these descriptors.

The technical function is only requested in the TCC since 2016, i.e. all older dossiers which have not been updated until now may not include this information.

Within IUCLID and CHESAR, the technical function is reported for each exposure scenario. If one exposure scenario includes different products (even with the same PC code) it remains somewhat unclear to which product the TF relates. This is particularly the case if several TFs are given. The following example (from IUCLID file of ECHA’s example substance[^184]) shows three TFs which may relate to both waterborne and solvent-rich paints or it is possible that e.g. the TF as a defoamer relates only to the waterborne paint, while the other two TFs relate to the solvent-rich paint.

Currently, the registrant has no other way to present the information in the structured fields, but can only clarify the relation between TF and PC in free text fields, e.g. in the ‘further description of the use’. The same basically applies to article service life scenarios in which registrants may include different articles (with the same or different ACs) into one scenario but can only provide a single TF in IUCLID.

These examples illustrate that the TF per mixture or per material (article) may not be evident, if registrants use broad exposure scenarios, such as ‘Consumer use in adhesives, coatings and inks’ or ‘Service life (consumers) for rubber and plastic articles’.

The ECHA identified some shortcomings in the use descriptors of the TF in the R12 guidance, including that some terms are difficult to understand, some are not used at all, and others appear to be too broad or not correspond to the industry’s terminology. Hence, it is likely that the TFs are not always correctly used giving rise to some uncertainty about the identified functions.

**Availability of the information in the supply chain**

The intended technical function of a substances is known to the registrant and provided in the registration dossiers (after 2016 subject to TCC). The technical function may be directly related to PCs/ACs in one exposure scenarios it this is narrow or if a substance has only got one function.

Functions and uses in PCs and ACs that the registrants do not identify may exist in the market as innovative and potentially confidential use. In general, any non-identified use is unlikely to be communicated upstream if this is considered a loss of sensitive business information. In addition, the only incentive to communicate upstream would be to have a use included in a registration dossier (i.e. prevent the need to make a DU CSR or change the substance use).

Information on such non-identified (confidential) uses may be available only to the actor implementing or may be known also downstream. For example, if the non-identified use is developed in a cooperation between formulator and article producer, both actors are information holders about the (additional) TFs and in which PCs and ACs the substance is used in. The number of unidentified uses is likely to depend on the substance.
**Uses & exposures**

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### Availability of the information in other sources

Information on the technical function(s) of a substance may be retrieved from literature. In addition, informal or formal consultation with industry stakeholders would be an appropriate approach to gather this information, in particular for restriction proposals.

### Consequences of current information gaps

If information on the TF as such and/or the function in relation to a particular PC or AC is not available, substances cannot be assigned to use-based groups.

Currently, for the identification of priority substances for regulatory risk management, substances may:

- not be identified as regulatory candidate at all. If they are used instead of a substance within that group and their hazards are similar or worse, regrettable substitution may occur.
- be identified as regulatory candidate but not as a member of “their” group but individually. This may result in increased resource needs (additional restriction proposal) and inconsistencies in regulation as compared to other, similar substances and across markets.

In lack of information on the TF, the selection of an appropriate regulatory instrument may be hampered because the breadth of application areas and the technological relevance of the substance may not be fully clear.

Restriction proposals may be wrongly scoped if information on the TF is missing because the identification and assessment of the available, suitable alternatives will be uncertain. To prevent wrong scoping authorities may invest in own research or await information via the consultations.

### A2.1.6 Information on intended transformation due to the technical function

This section discusses transformation that is a result of the intended function of a substance, such as cross-linking agents, intermediates, or antioxidants (and also including the generation of nano-forms). The decomposition and (bio-)degradation of substances is not considered use and exposure information but rather relating to the hazard of a substance.\(^{185}\) This is therefore not discussed here.

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\(^{185}\) If a substance degrades, the degradation products are to be considered in the exposure and risk assessment. Although this is relevant exposure information, it is not in the focus of this study as it does not concern exposure related to a use but rather exposure related to the substance properties.
**Information needs**

Information on whether a substance is intended to transform during its use (due to its technical function) indicates which of its life cycle stages (LCSs) are relevant and thus enables plausibility checking of other use pattern information. Furthermore, it indicates the potential for a change in hazard (and related risks) along the life cycle of the substance as if only the parent substance were considered. Information on the specific transformation products (and their hazard profile) allows an assessment of whether the hazard changes and in which direction, and consequently to refine any exposure and risk assessment.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Monitor policy impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended transformation</td>
<td>Identify exposure potential / get indication of risk</td>
<td>Scoping restriction</td>
<td>Not needed</td>
</tr>
<tr>
<td></td>
<td>Relevance of life cycle stages</td>
<td>Supports identification of relevant LCSs and uses</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reduced or increased risk after transformation</td>
<td>Risk assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Facilitates structuring risk assessment, potential need to assess transformation products</td>
<td></td>
</tr>
</tbody>
</table>

**Availability of information in the registration dossiers**

**Legal requirements**

According to Annex I, Section 6, the intended transformation of a substance during the use should be specified in the CSR, including a characterisation of the transformation (and degradation) products. Additionally, an assessment of related exposures is required. Information on the occurrence and the identity of the transformation products is not normally available for substances that do not require a CSR that are registered below 10 t/a or that are not classified as hazardous.

It should be noted that the term “transformation” or “transformation product” is not defined under REACH and therefore, the term may be subject to different interpretation by different actors.

**Implementation in registration**

Due to the legal requirement to provide information on transformation products, it should be included in the CSR. However, it appears to be only rarely provided in the CSR. The CSR as such is subject to the TCC since 2021.

**Availability of information in the supply chain**

In some cases, the registrants know, based on the intended technical function and application areas, if the substance should transform during its use (although this may not always be the case, in particular for transformation into nano-forms by DUs). Depending on the type of substance and the nature of the transformation, the identity of the transformation products may be deductible for the registrant, based on the molecular structure and the type of intended reaction. The identification of

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186 Annex I Section 6 also requires an overall assessment of risks from the substance (including its transformation products), thus implicitly also requiring a risk assessment.

187 The classification of substances should be based on “all relevant information” but the legal text of the classification and labelling regulation only refers to the substance as such and not its transformation products. Hence, hazardous transformation products are unlikely to trigger a classification. An exemption may be harmonised classifications driven by the authorities, where such assessments may be made, in particular for PBTs/vPvBs.
transformation products is particularly challenging for the registrants, if it reacts with other substances, rather than just “decomposing” or being oxidised. In the latter case, the actors at that lifecycle stage, where the transformation occurs may have more detailed information about the transformation products. However, this again depends on the type of transformation, the type of use and, not least, the competences of the user.

![Figure 7: Availability of information on the technical function along the supply chain](image)

**Availability of information from other sources**

Information on the intended transformation of substances may be deductible from the substance function. Information on transformation products may be available in databases for those substances, that are merely oxidises or reduced but not those, where complex reactions with other substances take place.

**Consequences of current information gaps**

If the authorities do not know if a substance is intended to transform and, if this is the case, which identity the transformation products have, it remains uncertain if

- a substance might need regulatory risk reduction measures, which may lead to overlooking potential regulatory candidates or prioritising substances, that are not relevant
- higher or lower risks could occur during the use because it is unknown if transformation products that are more hazardous than the parent compound. Hence, in identifying the appropriate measure and in drafting restriction proposals risks may be
  - overestimated triggering unnecessary measures or
  - underestimated potentially in damage to human health or the environment and/or delayed risk management.

**A2.2 Information on tonnages**

Information on tonnages concerns:

- Total consumption volume in the EEA (registered tonnage minus exported tonnage as such, in mixtures and in articles)
- Tonnage per LCS
- Tonnage used as intermediate / covered by legislation
- Tonnage per group of uses and/or per product category (AC/PC)
- Tonnage per use at higher granularity as AC/PC

**Information needs**

For the assessment of regulatory needs, the authorities need information on the overall consumption volume (manufactured and important tonnage minus export tonnage) as an exposure proxy to rank overall action needs. In addition, it indicates the extent of market impacts of a potential regulatory measure. The consumption could be deducted by subtracting exported amounts and use amounts as intermediates from the total registration volume.

Information on total tonnages entering a particular life cycle stage (consumer, professional and/or industrial uses and service life) and, at a higher granularity the tonnages per use and/or per PC/AC allow weighting the relevance of different uses (with certain exposure potentials indicated by PC/AC) against each other. Furthermore, if tonnages can be assigned to uses (PCs/ACs) that are considered sufficiently regulated by other legislation, these amounts could be deducted from the overall amount potentially requiring regulatory action. The information on tonnages is hence closely related to the granularity of use reporting (cf. Section A2.1).

The changes in overall consumption volumes and tonnages entering specific life cycle stages and/or uses are key indicators of the regulatory success and hence needed as time trends for monitoring of policy success.

Drafting restriction proposals needs tonnage information as input to the risk assessment as well as the assessment of socio-economic impacts. Both processes need the information at a higher granularity than the impact assessment and assessment of regulatory needs to demonstrate risks are not adequately controlled and/or benefits of a measure outweigh the implementation costs.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Monitor policy impacts</th>
</tr>
</thead>
</table>
| Total consumption volume | Identify exposure potential / get indication of risk  
Exposure proxy, indication of widespread use | Risk assessment  
Input to risk assessment  
Assessment of share of volume addressed by a specific restriction  
SEA  
Input data to estimate benefits and costs | Measure use reduction  
Time trend |
| Tonnage per LCS | Identify exposure potential / get indication of risk  
Weighting exposure potential regarding the user groups (and service life) and the specific products a substance is used in  
Decision on regulatory instrument  
Relevance of user groups / service life and products that require regulation indicates whether specific or rather broad risk management approach should be taken | Scoping restriction  
Weighting of uses to decide what should be in or out of the scope | Measure use reduction per user group  
Time trends |
| Tonnage used as intermediate / other legislation | Identify exposure potential / get indication of risk  
Volume for which risk management is generally of low priority | Scoping restriction  
Exclusion of uses covered by other legislation from the restriction scope | Not relevant |
<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Monitor policy impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td><strong>Identify</strong> (potential) regulatory coverage**&lt;br&gt;Cannot be addressed by authorisation,**&lt;br&gt;<strong>volume that should not be covered by new measures</strong></td>
<td><strong>Restrictions</strong></td>
<td><strong>Monitor</strong>&lt;br&gt;<strong>policy impacts</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Decision on regulatory instrument</strong>&lt;br&gt;<strong>Low priority for regulation due to intermediate use / being already covered</strong></td>
<td></td>
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</tr>
<tr>
<td><strong>Tonnage used per PC/AC</strong></td>
<td><strong>Identify exposure potential / get indication of risk</strong>&lt;br&gt;<strong>Specific weighting of uses based on better understanding of exposure potential</strong></td>
<td><strong>Scoping restriction</strong>&lt;br&gt;<strong>Weighting of uses, decision on what should be covered or not</strong>&lt;br&gt;<strong>Risk assessment</strong>&lt;br&gt;<strong>Potentially sufficient as input to prioritise generic restrictions and as input to specific restrictions of substances with high hazard profiles</strong></td>
<td><strong>Measuring specific use reduction</strong>&lt;br&gt;<strong>Time trends</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Decision on regulatory instrument</strong>&lt;br&gt;<strong>Weighting of uses and better understanding of the impact of differently scoped measures would have on the overall exposure potential</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tonnage per product at higher granularity than PC/AC</strong></td>
<td>Not relevant</td>
<td><strong>Scoping restriction</strong>&lt;br&gt;<strong>Refining scope of specific restrictions</strong>&lt;br&gt;<strong>Risk assessment</strong>&lt;br&gt;<strong>Input information to assess if risks are adequately controlled</strong>&lt;br&gt;<strong>SEA</strong>&lt;br&gt;<strong>Input information to SEA</strong></td>
<td><strong>Measuring specific use reduction</strong>&lt;br&gt;<strong>Time trends may be needed, if a specific restriction should be evaluated</strong></td>
</tr>
</tbody>
</table>

**Availability of information in the registration dossiers**

**Legal requirements**

REACH Art. 10 and Art. 17/18 do not include explicit provisions with respect to reporting of the tonnage. However, Art. 10 refers to section 3 of REACH Annex VI that requires the registrant to provide ‘overall manufacture, quantities used for production of an article that is subject to registration, and/or imports in tonnes per registrant’ (section 3.1), ‘an indication of the tonnage used for his own use(s)’ (section 3.3) as well as ‘quantities of the substance in articles made available to DUs’ (section 3.4..)

**Implementation in registration**

At least the manufactured and/or imported tonnage is provided in REACH registration dossiers in IUCLID section 3.2 and is subject to the TCC. Such information is required for one year as a minimum, but information for several years – based on our experience – is sometimes provided. This allows checking time trends of the manufactured/imported tonnage in some cases. Additional tonnage information that may be provided in IUCLID section 3.2, but is not mandatory, include the tonnage directly exported, the tonnage used as intermediate under SCC as well as the ‘tonnage imported in articles’ and the ‘tonnage in produced articles’ (IUCLID section 3.2 wording).
For substances requiring a chemical safety assessment (i.e. ≥ 10 t/a) and an exposure assessment (i.e. hazardous substances) the tonnage for each use is required according to REACH Annex I and is also necessary for performing an environmental exposure assessment. The tonnage per use is generally reported in the Chemical Safety Report (CSR), which is attached in IUCLID section 13. While IUCLID allows to include the tonnage information per exposure scenario, providing this information in IUCLID sections 3.5.1-3.5.6 is not mandatory. If the exposure assessment is performed with CHESAR and the information is synchronised with IUCLID, the tonnage per use/LCS is available in IUCLID sections 3.5.1-3.5.6. In these cases, the following information is available in IUCLID section 3.5.0:

- Tonnage in industrial end-use: the tonnage from all industrial uses in IUCLID section 3.5.3 is automatically added up in IUCLID section 3.5.0.
- Tonnage in professional end-use: the tonnage from all professional uses in IUCLID section 3.5.4 is automatically added up in IUCLID section 3.5.0.
- Tonnage in consumer end-use: the tonnage from all consumer uses in IUCLID section 3.5.5 is automatically added up in IUCLID section 3.5.0.
- Tonnage in articles: the tonnage from all service life scenarios in IUCLID section 3.5.6 is automatically added up in IUCLID section 3.5.0.

For these LCS, registrants can tick a box in IUCLID section 3.5.0 to indicate that the tonnage reported is equal to the EU tonnage (across all manufacturers and importers).

If the tonnages for these LCS are not included in IUCLID section 3.5.0, they can be added up from the tonnages reported in the CSRs after manual extraction of the data.

At a higher level of granularity, tonnage information per use/LCS is available in IUCLID sections 3.5.1-3.5.6 as described above. For example, if CHESAR data are synchronised with IUCLID, the tonnage per use/LCS is available in these IUCLID sections (e.g. four tonnage values for four industrial uses in IUCLID section 3.5.3). However, the tonnage is only available per use/LCS, which may or may not coincide with the tonnage per PC/AC. For example, the tonnage per PC is available if a registrant develops exposure scenarios for every single PC. If, in contrast, the registrant provides an exposure scenario for several PC (e.g. hydraulic fluids (PC17), lubricants, greases, release products (PC24) and metal-working fluids (PC25)), the tonnage for each individual PC will not be available (also see discussion in section A2.1.5). Consequently, it will be impossible to identify the tonnage used in metal-working fluids (in this example). This issue applies to service life scenarios with one or several ACs assigned in the same way.

Again, if tonnage information is only provided in the CSR, the relevant information can be extracted manually, but the limitations discussed above apply as well (definition of the exposure scenario).

An even higher granularity of tonnage information will generally not be available in REACH registration dossiers. While PC sub-categories (as e.g. implemented in ECETOC TRA) are used for exposure assessment in some cases, they represent contributing scenarios to a given exposure scenario. Since the tonnage information is only provided (and, in fact, can only be entered) at the level of the exposure scenario (but not at the level of contributing scenarios), the following information will not be available:

- Tonnage used in mixtures per PC differentiated at least according to ECETOC sub-categories
- Tonnage used per AC differentiated at least according to ECETOC sub-categories

The only exception would be cases in which registrants define uses/exposure scenarios based on these sub-categories, which, however, is expected to be rarely the case.
A stricter requirement to define exposure scenarios/uses related to specific products/articles may be envisaged. This would not only allow gaining deeper insight into the specific uses and service life scenarios. For the reasons discussed above, it would also ‘automatically’ result in tonnage information of the substance in specific products and articles.

REACH registration dossiers do not differentiate tonnages by their release potential. While a differentiation of uses/LCS with low, middle and high releases may be achieved based on the ERCs assigned, this would require establishing a methodology (including cut-off values) to convert the default worst-case release factors in R.16 (ECHA, 2016b) into these three classes. Approaches for this purpose have been described in the literature (see Oltmanns et al., 2018; Schulze et al., 2018).

Tonnage information for uses covered by legislation addressing risks may or may not be provided in REACH registration dossier. For example, tonnage information for the consumer use of a substance in cosmetics would be included in a registration since the environmental risk assessment of substances used in cosmetics (in contrast to the human health risk assessment) needs to be performed under REACH.

Time trends of the tonnage used in specific PC, AC and their aggregations (e.g. tonnage used in all articles) will not be available in REACH registration dossiers. There are no fields into which such information could be entered unless registrants decide to provide this information in free text fields. However, such cases are expected to be very rare exemptions.

**Availability of information in the supply chain**

The registrants must provide information on the registered and imported tonnage and may provide tonnages used as intermediates (under strictly controlled conditions) as well as tonnages which are immediately exported. Only for substances that require a CSR and an exposure assessment, information on the tonnages entering industrial, professional and consumer uses (and service lives) are likely to be provided as they are used for environmental exposure assessments. If an exposure scenario is defined very broadly (including several PCs or ACs) no information is available per PC or AC. If an exposure scenario only includes one PC or one AC, the tonnage relates to this PC or AC. The higher granularity of product or article sub-categories (used to assess consumer exposure as contributing activities within an exposure scenario) does not involve tonnage information, since the latter is only provided at the exposure scenario level.

The tonnage information on the uses of substances, regardless of whether only for the own or accumulated for the market of all registrants, is currently compiled based on the marketing statistics of the registrants or the registrants’ estimates and assumptions driven by the need to demonstrate safe use in the CSR or a combination of both.

In general, the supply chain actors downstream of the registrant and/or distributors of substances have a less comprehensive overview of the use of substances in general but have more specific information on the substance volumes they use themselves and of the volumes they provide to their markets. DUs must report their production to the PRODCOM statistics and are likely to maintain a corresponding (or more differentiated) internal sales statistic. Volume information is considered confidential and thus unlikely to be communicated up the supply chain.

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188 The PRODCOM uses different reporting categories than the PCs and ACs under REACH and the information can therefore hardly be related. The business statistics are more aligned with the PRODCOM than the REACH use descriptors.
Availability of information from other sources

Information on the consumption volume of chemicals as well as the volumes entering specific uses and being covered by legislation are not easily available and accessible to the authorities from databases or similar sources. While EU production and trade statistics may contain some specific information on commodity chemicals, this information is missing for lower volume and specialty substances. For most substances this information is likely to be missing at all.

Consequences of current information gaps

The registration tonnage is generally available but due to a lack of regular updating requirements not considered as sufficiently up-to-date. This lack of up to data on the registration volume may hamper the identification of regulatory candidates (overlooking or overestimating risks).

The assumption of an obsolete tonnage in the prioritisation of SVHC for Annex XIV inclusion might result in an inappropriate prioritisation. This might delay addressing substances with higher exposure potentials and accelerate addressing substances with a comparably low exposure potential.

For the impact assessment of regulatory actions, time trend information is required on the registration volume. This may in rare cases be available from the registrants on a voluntary basis but is generally considered not available, due to a lack of respective updating requirements.

The tonnage information per use is, if at all, available at the level of a use. As it is unclear how the registrants generate the tonnage data (per use), due to the close interlink of tonnage information and the demonstration of safe use in the CSR, with a view to potentially quick changes in markets and the lack of updating requirements for this information, the tonnage information per use is not considered a reliable exposure proxy. Similarly, the currently available information on the tonnages covered under existing legislation is uncertain, as frequently no tonnages are reported per PC or AC, which would be a minimum to identify applicable legislation.

In lack of information on tonnages per use, the authorities may select inappropriate regulatory measures as they cannot identify which

- of the identified uses are relevant potentially resulting in a failure to address risks (early) or inefficient use of resources due to starting unnecessary regulatory processes
- share of a registered substance is already regulated or might be (better) regulated under other legislation, resulting in inefficient or less effective regulation or
- selecting a measure that does not address the correct life cycle stage; this may be relevant if information on the amount of a substance ending up in articles is missing.
Restriction proposals require information on the tonnage used per PC and/or AC, which can be published and used as input data for the risk assessment. The lack of up-to-date and specific use volumes may cause uncertainties in the demonstration of risk and may result a restriction scope that is not relevant, i.e. minor uses are included. Using obsolete or inaccurate use volumes from the registration dossiers in the SEA would result in inaccurate descriptions of costs and benefits of a restriction and may mislead the understanding of potential restriction impacts. In the worst case, restrictions could be adopted where the expected costs by far exceed the benefits.

Information on the volume per use might be used as additional information refining the scoring in the prioritisation of SVHC for Annex XIV inclusion. In lack of detailed and up-to-date information the score derived from the registration volume may mislead the prioritisation process, potentially accelerating the risk management process for substances with low exposure potentials or delaying that of substances with high exposure potentials.

The assessment of regulatory impacts needs time trend information. The more detailed the information is, e.g. tonnages used in PCs and ACs, the better can the market reactions be understood and, in case it becomes evident that the regulatory goal cannot be reached, the regulatory action be refined or modified. In this regard, a high frequency of updates of information at a medium level of granularity (i.e. ACs at the material level) would be helpful. If this information is not available, ex post impact assessments either require specific additional data collection or incorporate uncertainties.

### A2.3 Information on the CoU

#### Needs

The CoU (CoU) are differentiated into information

- related to the PC/AC a substance is included in (physical state, concentration, release potential indicated by inclusion in matrix (if relevant)
- on the operating conditions during (industrial, professional and consumer use as well as service life)
- on RMMs implemented to reduce emissions and exposures.

Information on the CoU is related to the information on emissions and exposures.

Information on the CoU is not needed to assess regulatory needs for substances with high priority hazards. However, for substances with less severe hazards, the assessment of regulatory needs may require a more detailed assessment of such information to conclude on the need for action. For this, the information that are closely related to the product, such as the concentrations in mixtures and articles, or the binding to a matrix may be used as to conclude on a regulatory need.

Information on the CoU is not used for the prioritisation of SVHCs for inclusion in Annex XIV.

Monitoring of policy impacts may, depending on the nature of the regulation, require information on changes of the CoU, mainly regarding the type of RMMs applied or changes in the concentrations in mixtures and articles.

The main need for detailed information on the CoU stems from the restriction process, where the demonstration of risk and that existing RMMs are not sufficient is a precondition. However, as the aim of the CSR is to demonstrate safe use, it is unlikely that information supporting the contrary could be found in registration dossiers. The information also supports any scoping of specific restriction
conditions and the development of a socio-economic analysis of the potential impacts of a restriction. Generic restriction proposals (REACH Art. 68(2) or future GRA) do not require information on the CoU.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Monitor policy impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state of mixtures containing the substance</td>
<td>Identify exposure potential / get indication of risk Indication of mobility during use</td>
<td>Scoping restriction Could be relevant for defining restriction scope or conditions Risk assessment Input to risk assessment</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Average concentration in products (PC/AC)</td>
<td>Identify exposure potential / get indication of risk Indication of high exposure potential</td>
<td>Scoping restriction Could be relevant for defining restriction conditions Risk assessment Input to risk assessment</td>
<td>Policy success Time trend if concentration is targeted by measure</td>
</tr>
<tr>
<td>Type of matrix integration</td>
<td>Identify exposure potential / get indication of risk Indication of likelihood and extent of release during use and/or service life</td>
<td>Risk assessment Input for exposure models and/or determining migration rates; further information on the location in an article may be needed</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Exposure driving conditions during use</td>
<td>Identify exposure potential / get indication of risk Indication of likelihood and extent of release during service life</td>
<td>Scoping restriction Could be relevant for defining restriction conditions Risk assessment Input to risk assessment</td>
<td>Policy success Time trend if conditions are target of measure</td>
</tr>
<tr>
<td>Exposure driving conditions during service life</td>
<td>Identify exposure potential / get indication of risk Indication of likelihood and extent of release during service life</td>
<td>Scoping restriction Could be relevant for defining restriction conditions and grouping uses Risk assessment Input for exposure models and/or refining release rates from articles</td>
<td>Policy success Time trend if conditions are target of measure</td>
</tr>
<tr>
<td>Operational conditions and RMMs</td>
<td>Identify exposure potential / get indication of risk Could be relevant if substance is only used in industrial uses to identify regulatory need Identification of regulatory instrument Could support selection of appropriate measure in the field of workers health and/or the environment</td>
<td>Scoping restriction Could be relevant for defining restriction conditions and grouping uses Risk assessment Input for exposure models and/or refining release rates from articles</td>
<td>Policy success Time trend if conditions are target of measure</td>
</tr>
</tbody>
</table>

**Availability of information in the registration dossiers**

**Legal requirements**

Section 3 of REACH Annex VI does not specifically address the CoU (CoU). However, relevant CoU need to be communicated down the supply chain by means of the exposure scenario annexes to the safety data sheet. This is intended to ensure that a substance is – for example – not used at concentrations higher than the ones found to be safe in the chemical safety assessment. For substances requiring an exposure assessment, REACH Annex I defines requirements with respect to the CoU, such as RMMs, activities by workers and consumers as well as duration and frequency of exposure.
Implementation in registration

For a substance requiring an exposure assessment, a set of CoU will need to be defined for each contributing activity in each exposure scenario. However, providing this information on the contributing activities in IUCLID sections 3.5.1-3.5.6 of the REACH registration dossier is not mandatory. While relevant fields are available in IUCLID, they are apparently populated only very rarely, and the information is only contained in the Chemical Safety Report (CSR) attached in IUCLID section 13. Since CoU represent important inputs for the exposure assessment, they form part of the exposure assessment in CHESAR. In this context, it is important to understand that CHESAR provides the option not to export the ‘exposure information’ (which include the CoU) when exporting uses to IUCLID. Based on our experience, this option is generally used by registrants and the ‘exposure information’ per contributing activity (i.e. CoU, release and exposure estimates) is not exported even if the uses are exported from CHESAR to IUCLID.

In the best case, the following information needs are covered in IUCLID sections 3.5.1-3.5.6 of registration dossiers if the fields in contributing activities are adequately filled in.

- Concentration in the mixture
- Physical state of the mixture
- Concentration in the article
- Indicators of conditions driving exposure, such as the operating temperature, level of containment of a process etc. (to the extent applied in exposure assessment and used in the exposure assessment tool)
- OCs/RMMs during uses and waste processing at the level of ECETOC TRA or specific determinants (SPERCs, SWEDs, SCEDs)

If the information is not available in IUCLID sections 3.5.1-3.5.6, it is available in the CSR attached in IUCLID section 13. In both cases, completeness of the information may be variable, and some information may be missing. Missing information is expected to be less likely if CHESAR is used and exposure information is exported to IUCLID, since CHESAR-based exposure assessments require key information to be filled in.

Several information needs are not covered by registrations, since they do not represent information requirements and no IUCLID fields are available (unless provided by registrants in free text fields, which, however, is expected to be rarely the case):

- Binding in the matrix
- Information on the workplace conditions implemented in practice
- More specific indicators of service life conditions driving human or environmental exposure, e.g. location within an article

All of that information is not normally updated on a regular basis and/or after changes in the regulatory status of an information, i.e. no time trends are normally available.

Availability of information in the supply chain

The information available to the registrants on the CoU mainly corresponds to the default values used as input to the exposure assessment (ECETOC TRA, use maps etc.). Whether and to what extent this

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189 In contrast, the TF and the tonnage per use are exported, even if the ‘exposure information’ is not exported.
information corresponds to the implemented CoU in the market is unclear, as the upstream communication on uses does not sufficiently work.\textsuperscript{190}

Each downstream user has information on the CoU he implements in the own processes. Formulators that closely cooperate with or consult their customers in the development and use of mixtures may be aware of the CoU at their customers’. Formulators and article producers should know at least the average concentration range of the substance in the mixtures or articles they produce as well as have indications of the emission potential based on the matrix a substance is include into or onto and the type of binding to that matrix. In some cases and for some uses, also measured or modelled migration rates may be available.

\textbf{Figure 9: Availability of information on the CoU along the supply chain}

<table>
<thead>
<tr>
<th>Conditions of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registerant</td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Importer of substances</td>
</tr>
<tr>
<td>Distributor of substances</td>
</tr>
<tr>
<td>Formulator of mixtures</td>
</tr>
<tr>
<td>Importer / distributor of mixtures</td>
</tr>
<tr>
<td>User of mixtures</td>
</tr>
<tr>
<td>Producer of articles</td>
</tr>
<tr>
<td>Importer / retailer of articles</td>
</tr>
<tr>
<td>Assembler</td>
</tr>
<tr>
<td>import, retailer of complex objects</td>
</tr>
</tbody>
</table>

Arrows indicate potential information flows upstream, crossed out = ‘does not take place’, dotted lines light cross = some information flows

Generally, information on the CoU are not considered confidential, with the exception of (exact) concentrations of substances in mixtures and/or when the CoU would allow concluding on innovative applications or processes. Registrants could get feedback on their CoU from the supply chain. However, the current communication requirements have not triggered this communication.

\textbf{Availability of information from other sources}

Information on the CoU of industrial processes may be available in the literature, such as the BREF documents, sector information or from inspections, technical reports etc. Information on the conditions of service lives may be ‘simple’ for many consumer articles but less known and obvious for articles that are part of machinery, applied under extreme conditions or which are parts of complex objects. In any case, this information is not easily accessible and would have to be researched case by case, which could be adequate to support a restriction proposal.

Information gathering directly from the industries appear to be more promising because data gathering is possible via questionnaires, in informal or formal consultations. Similar to literature research, this type of information gathering is cumbersome and probably only realistic to support restriction proposals.

\textbf{Consequences of current information gaps}

The uncertainties about the correlation between the default CoU provided by the registrant and the CoU implemented in the market affects several regulatory processes.

\textsuperscript{190} As indicated above, this is due to a lack of information flows on mixtures that could trigger a feedback upstream if a use is not covered, the fact that the CoU may be so generic that any use would be covered and/or the conduction of DU CSRs, which only trigger a notification to the ECHA but no response upstream.
A lack of CoU that could be used as exposure proxy, such as the concentration in mixtures and articles, the physical form of mixtures, or the type of matrix binding hampers refinements of initial exposure estimates, which might change the priority of substances for regulatory risk management. For example, worst case assumptions on exposure potentials from articles cannot be refined resulting in an too high priorities for risk management. Consequently, lack of that information may result in overlooking, delaying or wrongly accelerating regulatory risk management of substances.

A lack of realistic information on CoU might result in an inappropriate scoping of a restriction proposal, a potentially wrong outcome of the risk assessment and/or wrong assumptions for the SEA. Such erroneous assessment and assumption may be discovered in the consultation of the proposal. Where risks are overestimated, or benefits underestimated market actors will comment to justify the continued use of a substance. This could cause higher resource needs of the authorities than if the information was available and correct from the start.

### A2.4 Information about emissions estimates

This section addresses information that can be used to model emission from products and processes, such as migration rates from matrices, or that are measured.

**Needs**

Information on emissions is mainly needed for drafting restriction proposals. This data supports the demonstration of (which) uses are not adequately controlled and require addressing and are the basis for developing benefit estimates of a potential regulatory measure. The trends in emitted amounts of substances are needed to monitor policy success, in particular as an indicator of decreasing pressure from PBT and vPvB substances.

Information on the total amounts of a substance emitted to the environment (per use) could support the assessment of regulatory needs by refining a weighting of uses based on tonnage information. As the prioritisation process should be kept simple, the use of emission information in recommending SVHCs for authorisation is possible, but this is not needed.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Monitor policy impacts</th>
</tr>
</thead>
</table>
| Release rates from processes | Identify exposure potential / get indication of risk
Exposure proxy indicating emission potential to workplaces and (eventually) the environment | Risk assessment
Input to emission modelling / models | Not relevant |
| Release rates to the environment per AC | Identify exposure potential / get indication of risk
Exposure proxy ascertaining an assumed release from service life | Risk assessment
Input to emission and exposure modelling | Not relevant |
| Modelled total emitted amount to the environment | Identify exposure potential / get indication of risk
High emitted amounts indicate high exposure potential in the environment | Risk assessment
Input to emission and exposure modelling
SEA
Base data to estimate benefits of restriction | Policy success
Time trends indicate if measure reduced environmental pressure |
| Measured total emitted | Identify exposure potential / get indication of risk | Risk assessment
Input to emission and exposure modelling | Policy success
Time trends indicate if |
### Need for Information

<table>
<thead>
<tr>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Monitor policy impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>High emitted amounts indicate high exposure potential in the environment</td>
<td>SEA</td>
<td>Base data to estimate benefits of restriction, measure reduced environmental pressure</td>
</tr>
</tbody>
</table>

### Availability of information in the registration dossiers

#### Legal requirements

The characterisation of emissions (i.e. releases) of a substance is required by REACH Annex I for (a) PBT/vPvB substances and (b) all substances for which an exposure assessment is required\textsuperscript{191}. According to the provisions of section 5 of this annex, ‘emission estimation shall consider the emissions during all relevant parts of the life cycle of the substance resulting from the manufacture and each of the identified uses’, including the waste stage.

#### Implementation in registration

Similar to the tonnage information addressed in section A2.2, information on emissions to the various compartments is required for all substances requiring a chemical safety assessment (i.e. ≥ 10 t/a) and an exposure assessment (i.e. hazardous substances; or PBT/vPvB substances (see above)). The following emissions are typically reported in registration dossiers of substances requiring an exposure assessment:

- Emissions to water and air at local scale (emissions to soil are not assessed at local scale)
- Total emissions\textsuperscript{192} to water, air, and soil from all LCS combined

These emissions are generally reported in the Chemical Safety Report (CSR), which is attached in IUCLID section 13. While IUCLID allows to include the emission information at the local scale for each exposure scenario in IUCLID sections 3.5.1-3.5.6 and total releases in IUCLID section 3.7, providing the information in these sections is not mandatory and is not subject to the TCC.

If CHESAR is used for the exposure and risk assessment, the emission information is available in the tool. If the CHESAR data are exported to IUCLID, the emissions discussed above are only exported to IUCLID sections 3.5.1-3.5.6 and 3.7 if the export of exposure information is not deselected. This represents a major difference of the tonnage information, which is exported even in this case. The reason for this difference is the fact that the tonnage is considered to be part of the use description, while emissions are handled as part of the exposure information.

If CHESAR data are fully exported to IUCLID (i.e. without deselection of the exposure information), IUCLID sections 3.5.1-3.5.6 contain the following information:

- Release rates per PC and emission route (air and water)
- Release rates per AC and emission route (air and water)
- Percentage of use volume emitted from articles (i.e. the release factor)

\textsuperscript{191} A substance considered to possess PBT/vPvB properties requires an assessment of emissions and exposure, even if it does not have to be classified according to the CLP Regulation. With the intended inclusion PBT/vPvB hazard classes in the CLP Regulation, this differentiation may become obsolete.

\textsuperscript{192} CHESAR and IUCLID use the term ‘release’ rather than ‘emission’, but there is no difference in the meaning of the two terms.
As noted earlier, this information will be available per exposure scenario (i.e. manufacture, use and service life scenarios). In cases where a single exposure scenario includes more than one PC or AC, the information will not be available for each of the PC or AC.

If the information above is not included in IUCLID sections 3.5.1-3.5.6 and 3.7, it needs to be manually extracted from the CSRs, in which it should be available. The local emissions are generally included in the exposure scenarios in CSR chapter 9.1, while the total releases from all LCS are typically included in CSR chapter 10.2.1<sup>193</sup>.

The emission information could be used to differentiate substances with high emissions and those with low emissions. In a first screening step, total emissions from all LCS (IUCLID section 3.7 or CSR chapter 10.2.1) could be used for this purpose. For example, a substance with total emissions to water in the range of many tonnes may be of higher priority than a substance with emissions to water of a few kilogrammes. Using total emissions, however, does not identify uses/LCS associated with particularly high emissions. These could be identified only based on the information per exposure scenario (IUCLID sections 3.5.1-3.5.6 or CSR chapter 9.1).

The following information needs are expected to be not or only very rarely reported in registration dossiers:

- Modelled or measured data of migration rates from a matrix
- Release rate of substance from article during the waste stage per emission route
- Time trends on emitted amounts per sector (and waste stage)
- Time trends on emitted amounts per PC and AC

**Availability of information in the supply chain**

The registrants’ information on the emission rates are in most cases the default values used as input to the exposure assessment (ECETOC TRA, ERCs, SPERCs etc.). Due to the nature of exposure assessment, where the conditions of safe use should be demonstrated and so called “realistic worst-case” assumptions are made at initial stages of an assessment, the release rates are usually conservative, i.e. overestimate the release. Consequently, also the calculated tonnages released from PCs and ACs as well as overall tonnages include uncertainties about the actual release.

The DUs might make better estimates of release rates due to more precise knowledge of the CoU, including mixture and/or article composition and the way, substances are included into them, but are not likely to have e.g. measured data on release rates. Similarly, the amounts emitted may only be available or could be made for the own processes regarding the environmental emissions. Specific data and models to determine emission rates may be available in some sectors, e.g. migration rates of substances from the food packaging sector or evaporation rates in car interiors. If (national) requirements exist on emissions to air or water, measured emission concentrations may be available that could be converted to emitted amounts using volumes of waste gases and waste waters.

<sup>193</sup> The current ECHA CSR template (available online: [https://echa.europa.eu/de/support/guidance-on-reach-and-clp-implementation/formats](https://echa.europa.eu/de/support/guidance-on-reach-and-clp-implementation/formats), same structure implemented in CHESAR) deviates from the CSR structure according to REACH Annex I. Apparently, use of ECHA’s is not considered to be non-compliant with the REACH Regulation, but the new structure should be implemented in the REACH Regulation.
Figure 10: Availability of information on emissions along the supply chain

Information on release rates and emitted amounts are not likely to be considered confidential information.

**Consequences of current information gaps**

Information on emissions is not normally used in the assessment of regulatory needs. Reliance on default values from emission models which are likely to rather overestimate than underestimate releases to the environment may result in prioritising substances for regulatory risk management which are not actually causing risks. Authorities would unnecessarily spend resources.

For restriction proposals, input information to risk assessments may be too conservative and authorities which may confound the risk assessment as well as the SEA relating to its results. The monitoring of policy impacts would suffer less from the existence of more realistic emission information, as the change of released tonnages are important and, at least if modelled information is used, would be derived based on the same input values.

### A2.5 Information on Exposures

**Needs**

As for the information on emissions to the environment, exposure information is mainly relevant for the drafting of restriction proposals. As the modelled exposure levels are based on the release rates provided in the registration, they are associated with the same uncertainty about overestimating exposures. Measured data on exposure levels has a more prominent role for the environmental and health risk assessment, as it may be used as main evidence or to modify risk conclusions from modelled values.

Time trend information on exposure levels would be helpful to the impact assessment, particularly for human health, but also for the environment for non-PBT/vPvBs.

<table>
<thead>
<tr>
<th>Need for Information</th>
<th>Assessment of regulatory needs</th>
<th>Restrictions</th>
<th>Monitor policy impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modelled exposure levels in humans and the environment per use</td>
<td>Not relevant</td>
<td>Risk assessment&lt;br&gt;Core information to demonstrate risks are not adequately controlled and need addressing&lt;br&gt;SEA&lt;br&gt;Basic information to estimate benefits of a restriction</td>
<td>Policy success&lt;br&gt;Time trends</td>
</tr>
</tbody>
</table>
### Availability of information in the registration dossiers

**Legal requirements**

REACH Annex I defines the requirements for the exposure assessment as follows: ‘An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is known or reasonably foreseeable. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. Such estimations shall take account of spatial and temporal variations in the exposure pattern.’ According to section 0.6.3 of REACH Annex I, an exposure and risk assessment is not only required for substances that are classified for the hazard classes defined in that section, but also for substances ‘assessed to be a PBT or vPvB’.

**Implementation in registration**

In principle, the issues discussed above for emission estimates (section A2.4) apply to exposure (estimates) as well. Thus, exposure estimates are required for all substances requiring a chemical safety assessment (i.e. ≥ 10 t/a) and an exposure assessment (i.e. hazardous substances; or PBT/vPvB substances (see above)) and these exposure estimates are generally reported in the Chemical Safety Report (CSR), which is attached in IUCLID section 13. IUCLID allows for inclusion of the exposure estimates for each contributing activity in each exposure scenario in IUCLID sections 3.5.1-3.5.6 and 3.7 (for regional environmental exposure) but providing the information in these sections is not mandatory and is not subject to the TCC. Based on our experience, inclusion of exposure information in these IUCLID sections is rarely used by registrants. Even if registrants use CHESAR for the exposure and risk assessment, export of the exposure information to these IUCLID sections is expected to be often deselected (an option specifically provided for by CHESAR).

The following exposure information is typically reported in registration dossiers of substances requiring an exposure assessment (usually in the CSR):

- Modelled exposure levels in humans and the environment per use (for each contributing activity)
- Measured exposure levels per use and measured exposure levels (monitoring data) in humans and the environment
- RCRs for human health and the environment

As noted above, this information will only be contained in the CSRs in most cases. If the data are reported in IUCLID sections 3.5.1-3.5.6 and 3.7, the following should be noted: (a) only information of the main assessment\(^{194}\) will be included, but not any supportive assessments (e.g. when measured

\(^{194}\) The terms ‘main’ and ‘supportive’ reflect the CHESAR terminology for different exposure estimates.
data are used as supportive evidence); (b) RCRs are not reported in these IUCLID sections, but are only presented in the CSRs.

**Availability of information in the supply chain**

Generally, DUs may derive more realistic modelled exposure levels at workplaces or in the local environment if they used exposure models with their specific situation as input information. In addition, measured workplace exposure levels may be available for those substances, where (national) requirements exist in OSH legislation. Measured exposure levels in the environmental media are unlikely to be available.

![Figure 11: Availability of information on exposures along the supply chain](image)

Exposure information is not likely to be considered confidential.

Measured data at workplaces and in the environment may be available (for some substances) from (national) monitoring programmes and/or in research institutions, as well as from agencies and authorities working on occupational health and safety.

**Consequences of current information gaps**

The lack of reliable modelled exposure information and a lack of measured data at workplaces hampers the development of reliable risk assessments in the drafting of restriction proposals, potentially resulting in inappropriate restriction scopes and regulation that addresses only minor risks. Time trends would be most important from measured data to monitor regulatory impacts because the modelled data would mainly reflect the changes in the market.
The long list of policy options is based on the information gaps assessment. The long list of policy options is structured according to the information categories identified as relevant in the needs and gaps assessment and the specific types of information pertaining to each of the categories that support the regulatory processes. At the end of the section specific information needs for the restriction process according to REACH Art. 68(1), 68(2) or 69 (prioritisation of products/articles demonstration of risks and assessment of socio-economic impacts) are provided. The drawback of presenting the options in this way is that the list is quite long, contains doublings, where one option is applicable to several information types (e.g. technical optimisations are possible for various information items) and makes the understanding of interlinks between options difficult. Therefore, overarching options are presented first (Section A3.1) and options that improve the interlinks between information (e.g. plausibility checks) are presented at the end of each section addressing one information category. When options are interlinked, e.g. registrants could be required to provide information but need information from DUs to increase the level of detail or decrease uncertainty of information these interrelations are indicated in the long list.

Note: the list of policy options was developed as an interim result of the project. When the policy options were developed, the initial options listed here were partly further developed, differentiated or reduced. Therefore, the options in the long list do not fully correspond to the options described in Section 6.

A3.1 Overarching options

A3.1.1 Requirements for updating of registration dossiers

Up-to-date information on the use pattern (and tonnages) is important to ensure the decisions on regulatory needs and the selections of appropriate regulatory instruments are based on relevant information. Time trend information that can only be derived if the registration data is regularly updated would not only support policy success monitoring but also allow identifying changes in the market that increase or decrease the urgency of regulatory action e.g. restriction proposals. The dossier updating requirements may be linked to the frequency of additional requirements for the DUs to report use and exposure information to registrants and/or to the authorities.

Description of the options and sub-options

Updating requirements could differ according to the periodicity

a) on a regular basis (e.g. annually, biannually, every 5 years),
b) after new requirements come into force
c) upon another regulatory triggers (e.g. notification of an intention to make an evaluation, draft a restriction proposal but also upon notice by ECHA that up-to-date information is needed to assess the regulatory need)
d) new information on tonnages (per use) is available (within a certain range, e.g. 25% of the own registration volume)
Implications

Legal changes: adaptation of the REACH enacting terms or of the implementing regulation on dossier updates. Sanction mechanisms are needed to enforce the requirement either at EU level by withdrawing registration number or at national level.

Target processes: Assessment of regulatory needs (ARN, prioritisation of SVHC for Annex XIV, restriction, policy success monitoring

Specific challenges (other than resource needs): Update of joint registration needs organisation of updating process in the consortia.

Interlinks with other options: updating can be implemented independent of other options but the extent of the update is determined by which other (additional) options are implemented.

A regular updating requirement of the registration dossiers corresponds to the production and use reporting under the Toxic Substances Control Act (TSCA) in the US. The US ‘Chemical Data Reporting’ (CDR) requires manufacturers and importers to report every four years on their annual production and import volumes, if these exceed the defined threshold (generally > 11.3 t/a, or > 1.13 t/a for regulated substances or substances undergoing a regulatory process). Information on the volumes used in industrial, consumer and professional uses are to be reported per year, subject to the same tonnage thresholds.

Initial evaluation: inclusion in the impact assessment

- No legal provisions that prevent the implementation of the options
- Option would ensure that registrants are provide up-to-date information for use in all regulatory processes
- Due to TCC, registration dossiers that have not been updated in a long time would be more relevant

A3.1.2 Transfer of exposure assessment into IUCLID

Exposure assessments in the CSR is currently not or only partly available in IUCLID section 3.5, because a) not all registrants use Chesar, and b) those who do frequently do not allow the import of that information. Therefore, available information is not (easily) accessible for the regulatory processes.

Description of the options and sub-options

a) Make Chesar obligatory as CSR tool and require that all relevant information from the CSR be transferred to IUCLID or

b) If Chesar should not be made obligator, make the (manual) inclusion of all relevant exposure assessment information into IUCLID obligatory, including detailed use descriptions per LCS, specific exposure determinants (e.g. concentration in the mixture, operating conditions driving exposure (e.g. operating temperature, containment of processes, location of use in case of service lives) and make the relevant fields subject to TCC

The benefits and efforts of this option depend on the level of detail of exposure scenarios (ESs) and the (additional) specification of e.g. exposure determinants, which is further discussed in the Sub-Section A3.2 on information on the use pattern. If the granularity of exposure scenarios is increased,

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e.g. by allowing only one PC and AC to be assessed in one ES, then use and exposure information would be available at high granularity.

**Implications**

**Legal changes:** Option a): include the use of Chesar under Article 111 or make it obligatory via the TCC. Option b): either implement changes in IUCLID and make subject to TCC and/or make explicit references to needed information in Annex I

**Target processes:** ARN, prioritisation of SVHC for Annex XIV, restriction, policy success monitoring

**Specific challenges (other than resource needs):** -

**Interlinks with other options:** option can be implemented independent of other options, which data would be covered is specified in options according to detailed information needs.

**Initial evaluation:** option potentially relevant but alternative option (A3.1.3) more promising; no further assessment

- No legal provisions that prevent the implementation of the options
- Registrants may have to gather some additional data to clarify uses from the DUs, in some cases they may not get it due to confidentiality
- Registrants will in many cases estimate tonnages
- Improves use information without changing the CSR structure and approach, i.e. the basis for downstream communication remains

**A3.1.3 Require the life cycle tree at higher granularity and independent from the CSR**

Authorities need a clear understanding of how the substance is used and more granular tonnage data to better weight uses against each other.

**Description of the options and sub-options**

In the lifecycle tree, the PCs that are applied in a use, corresponding to one ERC must be specified and for each PC the TF must be indicated (a maximum of two). For the service life, the ACs must be provided. If there are more than one ERC per life cycle, the PCs/ACs must be provided separately per ERC. For each PC at one life cycle stage, the share of the registration volume must be provided that is used in an industrial, professional or consumer use, and in articles. Consistency checks ensure that the total share does not exceed 100% for the life cycle stage formulation as well as for the three life cycle stages industrial, professional and consumer use together. For the service life, registrants are required to provide additional exposure proxies per ERC/AC combination.

This option would improve the understanding of the various uses and the share of a substance entering different life cycle stages and uses. As the life cycle tree is NOT connected to the CSR, the exposure assessment does not have to be changed; consistency checks should ensure that the CSR is in line with the life cycle tree, however.

**Implications**

**Legal changes:** a change of REACH Annex XI is needed to create a legal basis for providing tonnage information / percentages of the registration volume entering a use
**Target processes**: ARN, prioritisation of SVHC for Annex XIV, restriction, policy success monitoring

**Specific challenges (other than resource needs)**: ensuring consistency of life cycle tree and CSR, check if information from Chesar can be imported still (but would need further work for achieving the intended granularity). Registrants may not have the information at sufficient detail but might provide estimates of the tonnages.

**Interlinks with other options**: option can be implemented independent of other options, which data would be covered is specified in options according to detailed information needs.

**Initial evaluation**: inclusion in the impact assessment

- No legal provisions that prevent the implementation of the options
- Registrants may have to gather some additional data to clarify uses from the DUs, in some cases they may not get it due to confidentiality
- Registrants will in many cases estimate tonnages
- Improves use information without changing the CSR structure and approach, i.e. the basis for downstream communication remains

### A3.1.4 Make the CSRs part of the joint registration dossiers

Under the current REACH provisions, the CSR may be provided as part of the joint registration or may be provided by each registrant separately. It is also possible that some uses are provided in a common CSR and some are assessed separately by individual registrants. This leads to inconsistencies across registration dossiers, specifically in the information about the use patterns.

**Description of the options and sub-options**

By default, a common CSR is to be provided as part of the joint registration dossier. Uses considered as confidential may be reported with an ‘opt-out’ CSR.

**Implications**

**Legal changes**: adaptation of REACH Art. 11.1 (include CSR under information to provide in the joint dossier) and Art. 11.3 (information types for which opt-out is possible)

**Target processes**: ARN, prioritisation of SVHC for Annex XIV, restriction, policy success monitoring

**Specific challenges (other than resource needs)**: Provision of joint CSR requires organisation and agreement in the consortia and/or coordination between lead and co-registrants.

**Interlinks with other options**: joint CSRs can be required independent of other options.

**Initial evaluation**: no further assessment

- Competition law prohibits discussions on uses and tonnages across the registrants, which excludes the option from further assessment

### A3.1.5 Reverse the burden of proof in the restriction process

Some use and exposure information needed to draft a restriction proposal (according to REACH Art. 68(1)) are not accessible to the authorities. One option to solve this problem is to start restriction
proposals with a broad scope (and allow significant changes to the scope during the process) and to define a procedure how and when market actors should submit information on the relevance of covered uses and a potential exemption need from the scope (exemption application like an AfA). This ‘pre-scoping’ could precede the regular restriction process and provide a stronger trigger for industry involvement than ‘only’ an entry into the ROI.

**Description of the options and sub-options**

A third restriction route is implemented or a ‘pre-scoping process’ for existing procedures under REACH that consists of several steps: 1) drafting and publication of a restriction proposal with a broad scope 2) defined period for the industries to provide evidence on relevant uses that (some) uses should be exempted from the scope by a) demonstration of safe use and/or argumentation that there is a lack of alternatives and the use is essential. At the end of this process, authorities would start drafting the restriction proposal (i.e. Annex XV) according to the current provision under Art. 68 or 69.

This option appears to be an intermediate between the restriction and the authorisation process and would depend also on the ability of the industries to organise a process of providing information on their uses. It would also (partly) address the authorities’ challenge of getting and evaluating information on alternatives.

**Implications**

**Legal changes**: adaptation of the REACH text (Art. 68 or 69) to either implement an additional type of restriction process or by enabling a ‘pre-scoping’ of restrictions. This also affects the justification of a restriction, as the initial scope would not be based on the demonstration of a risk but just a risk hypothesis.

**Target processes**: restriction

**Specific challenges (other than resource needs)**: borderline to GRA; justification of broad scope via ‘burden of proof’ may be difficult. There is a risk that restrictions may be decided for substances in applications that do not pose a risk which remain undetected if industry and associations fail to get involved to ask for exemptions from the restriction scope.

**Interlinks with other options**: implementation is independent of other options

**Initial evaluation**: covered in other contexts, no further assessment

- No legal provisions that prevent the implementation of the options
- New structures and approaches to restriction and authorisation covered under other projects

**A3.1.6 Improve upstream communication to better inform registrants**

The registrants lack specific information on the use pattern, the tonnage per use, the CoU and the emission and exposures from the use of their substances. The application of sector use maps and related SPERCS, SWEDs and SCEDs supports the chemical safety assessment but is not designed to reflect the specific conditions in the market.

The upstream communication on uses does currently not work sufficiently well. Among the reasons are that the trigger for communicating to suppliers – the lack of coverage by an ES – does not work. This is due to a) very broad exposure scenarios that basically cover “any use”, b) the lack of a method for checking conformity with a use as well as the lack of a clear definition of a use. Additional reasons
for insufficient upstream communication are confidentiality concerns, as well as a lack of awareness of the DUs.

One option to improve the registration dossiers could be to improve the upstream communication so that the registrants get better information to describe the use pattern and make their chemicals safety assessment.

**Description of the options and sub-options**

The trigger for upstream communication and the communication content is extended in Art. 34: any DU receiving a safety data sheet (with or without an exposure scenario) must inform the supplier of any uses to those identified in Section 1.2 of the safety data sheet, regardless of whether or not an exposure scenario is attached. The obligation to ensure conformity with the ES remain unchanged.

a) Communication to the immediate supplier, i.e. potentially several stages of the supply chain
b) Communication directly to the registrant of the substances, circumventing the actors in between

**Implications**

**Legal changes**: change of REACH Art. 34 to include a communication obligation upstream that is triggered by the receipt of an SDS

**Target processes**: ARN, restrictions, monitoring of policy success

**Specific challenges (other than resource needs)**: identification of registrants for the DUs (at the end of the supply chain) challenging to impossible

**Interlinks with other options**: implementation is independent of other options but would support all options that target improvements of the registration dossiers

**Initial evaluation: legally and practically not feasible, no further assessment**

- Competition law prevents detailed upstream communication on use patterns, regardless of whether through the supply chain or bypassing the supply chain
- It is frequently not possible to identify registrants for users of mixtures and all actors purchasing chemicals via distributors
- A large amount of communication would be triggered which is not manageable for the registrants to assess

**A3.1.7 DU use reporting to the authorities**

Registrants frequently lack information on the use pattern and the CoU along the supply chain of their substances. Generally, the more specialised a substance is, the more likely it is that registrants have information about their downstream uses. However, detailed use information (PCs and specifically ACs) as well as the CoU are not normally available to them (i.e. use of default assumptions in ERCs, PROCs etc.). Information on use patterns (including on tonnages and time trends) and CoU are needed to support all regulatory processes.

**Description of the options and sub-options**

DUs are obliged to report their uses of hazardous substances to the authorities. The obligation could be differentiated:
• Periodicity
  a) Annually, biannually, every five years
  b) Upon specific request of the authorities

• Scope
  a) Identity of hazardous substances used as such or in mixtures (as identified in the SDS)
  b) Identity of hazardous substances plus amounts included into each PC / AC in the own processes and/or used as processing auxiliary
  c) Any information on the use pattern, tonnages, CoU, emissions and exposures as well as number of own sites and exposed workers, if specifically requested by an authority

The reporting obligations could be limited to companies

• With a certain role, e.g. only formulators (and making use of PCN information)
• Companies with a certain turnover / number of employees; exclusion of professional users
• Only share of companies with alternating reporting periods, e.g. 50% of all companies alternating every two years (i.e. authorities receive information annually but only from 50% of all companies

A use reporting on hazardous substances (as identified in the safety data sheets of the suppliers) would provide a database for the authorities to make specific requests.

**Implications**

**Legal changes**: change of the REACH text or development of new legislation to implement DU reporting obligations to the authorities.

**Target processes**: ARN, prioritisation of SVHC for Annex XIV, restriction, policy success monitoring

**Specific challenges (other than resource needs)**: Building up an IT system to gather and manage DU information and merge it with the IUCLID data.

**Interlinks with other options**: the option can be implemented independently from other measures. Any DU reporting could feed into other options or make them superfluous. Reporting of the use of hazardous substances (without any other information) would grant access of the authorities to all DUs of a substance for specific requests.

**Initial evaluation: generally possible, inclusion in the impact assessment**

• No legal provisions that prevent reporting to the authorities
• DU would be burdened with a share of the information generation on uses; however, as they have that information and, in principle should also have it in processable form, this appears reasonable
• Good experiences with product registers in the Nordic countries, which are frequently one of the first information sources used by the authorities to improve their knowledge for restriction proposals. Due to the different focus (substances rather than mixtures), less efforts are needed than for a product register
A3.2 Information on use patterns

A3.2.1 Life cycle stages and main user groups

Information on the lifecycle stages and main user groups is provided via the IUCLID, also for registrations in the tonnage band between 1 and 10 t/a. The LCSs are important indicators of the type and type of exposed users and whether exposure from articles may occur.

Information deficits identified mainly concern the reliability and consistency of information in the registration dossiers.

Optimization of IUCLID (incl. TCC), CSR and guidance

Improvement of the R12 guidance addressing the most commonly observed inconsistencies, e.g. how to differentiate between professional and industrial uses.

Other options:

Include a definition of ‘professional use’ under REACH Article 3.

Implications

Target processes: ARN, prioritisation of SVHC for Annex XIV

Specific challenges (other than resource needs): -

Interlinks with other options: -

Initial evaluation: useful and simple, inclusion in the impact assessment

- Legal: no contradiction with existing law
- Information availability: should be available
- Practicability: easy implementation, clarification for all sides, supports implementation in general
- Alignment with policies: neutral

A3.2.2 Information on the technical function

The technical function (TF) is an indicator of which lifecycle stages are relevant allows use-based grouping (TF in relation to PC/AC), which could enable more consistency in regulation and avoid regrettable substitution.

Information on the technical function (TF) is available in dossiers submitted or updated after 2016 (date of inclusion of TCC rule for the TF). The TF use descriptors are evaluated by the authorities as partly too detailed, not compatible with the terminology used in the markets and in statistics, and partly too broad, resulting in uncertainties for the regulatory processes.

Optimization of IUCLID (incl. TCC), CSR and guidance

Update of ECHA’s R.12 guidance on use descriptors regarding the TF (e.g. delete too detailed TFs, differentiate too broad categories, align with terminology of the market); improve explanation of the differences between the TFs and the PCs; potentially align with OECD
Change of registration requirements:

Include an explicit reference to the TF into the REACH Annex I/Annex VI as a mandatory part of a substance’s use description in the registration dossier.

Implications

Target processes: ARN, restriction

Specific challenges (other than resource needs): -

Interlinks with other options: -

Initial evaluation: useful and simple, inclusion in the impact assessment

- Legal: no contradiction with existing law
- Information availability: should be available (chemistry of registered substance)
- Practicability: easy implementation, clarification for all sides, supports implementation in general
- Alignment with policies: neutral

A3.2.3 Information on the intended transformation

The intended transformation indicates which lifecycle stages are relevant and the potential need to assess risks from hazardous transformation products.

Registrants are required to report the intended transformation and identify (and assess) any hazardous transformation products in the CSR, where relevant. There is no IUCLID field to indicate that a transformation exists.

Optimization of IUCLID (incl. TCC), CSR and guidance

- Update ECHA’s registration guidance to clarify the meaning of ‘transformation product’ (as opposed to degradation products)
- Include a tick-box to flag an intended transformation (as part of the intended function) that is subject to the TCC; if an intended reaction takes place, in addition require identifying the lifecycle stage where the transformation is intended to occur
- Implement data field / infrastructure in Chesar to allow exposure assessment of transformation products, where relevant.

Change of registration requirements:

Clarify in Annex I/Annex VI and/or Art. 10a.iii that the use description must specify if the transformation of a substance is intended and during which lifecycle stage

Change of DU requirements:

Implement a requirement for DUs (e.g. via a change of REACH Art. 34) to provide registrants with information on the identity of transformation products if a substance reacts during their use either

- upon receipt of a safety data sheet or
- if a restriction proposal is notified and the registrant makes a specific request
**Implications**

**Target processes**: ARN, restriction

**Specific challenges (other than resource needs)**: identity of transformation products frequently not known, also not to the Dus. Such information may be considered confidential as they are likely to provide inform about the use process. Upstream communication unlikely and not enforceable.

**Interlinks with other options**: independent of other options

**Initial evaluation**: technical adaptations and registration requirement useful --> inclusion in the impact assessment; DU requirements not needed and realistic --> no further assessment

- Legal: no contradiction with existing law
- Information availability: should be available to the registrant (and the DU)
- Practicability: easy implementation, clarification for all sides, supports implementation in general; DU requirement challenging due to CBI, lack of awareness, lack of enforceability
- Alignment with policies: neutral

### A3.2.4 Information on product types and the sector of use

Several deficits were identified regarding the description of product types in which a substance is applied, such as: PCs and ACs may be incomplete and inconsistent (within one dossier and across dossiers), the PC picklist is not fit for purpose (some PCs too broad, some too specific, some superfluous), ACs do not sufficiently indicate an exposure potential. No significant issues were identified regarding the quality and application of SU.

**Optimization of IUCLID (incl. TCC), CSR and guidance**

- Revise the use descriptors for product categories (PCs) in ECHA’s guidance documents to ensure they are clear, understandable, compatible with industry’s terminology, reflect potential emission and exposure levels as well as the structure of existing legislation. Develop sub-categories for PCs covering broad uses. For example, the PC32 (Polymer preparations and polymer compounds) could be specified by sub-categories on the type of polymer. The PC1 (Adhesives, sealants) might either be split into several PCs or also further specified by sub-categories.
- Make the reporting of all PCs for end uses subject to the TCC, i.e. no exemption for industrial or professional uses
- Implement a new use descriptor to qualify emission levels to the environment (air, water, soil) and exposure levels (evaporation, migration/availability for dermal contact) from products (high / medium / low) that must be selected in conjunction with both PCs but specifically with all identified ACs

**Change of registration requirements**

- Require ESs to cover only one PC and one AC by clarifications in Annex I (and related guidance documents)

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196 Sub-categories on polymer types, such as PVC, PP, PE etc. would help understanding the use and particularly the exposure potential (during service life), as TV, PC and sub-category in the area of polymers already indicate whether or not a significant release could be expected.
• Make the use description an obligatory part of the joint registration (REACH Art. 10.1.iii and Art. 11.1. (opt-out))

**Change of DU requirements**

• Require DUs to report their uses upstream upon receipt of an SDS in case the therein specified PCs/ACs differ from the own uses and those of the customers, independent of whether the CoU in the ES cover their use
• Oblige DUs to report their use of hazardous substances (as identified to them via the SDS) to the ECHA based on PCs and ACs (with a specification of the TF) a) regularly or b) on request

**Other options:**

• Make information from the Poison Centre Notifications accessible about the product types within which substances are included in.
• Make use of the Nordic Product Registers / SPIN, e.g. in drafting restriction proposals

**Implications**

**Target processes: ARN, prioritisation of SVHC for Annex XIV, restriction, policy success monitoring**

**Specific challenges (other than resource needs):** Improved picklists will only significantly improve information, if registrant have access to the respective knowledge. Inclusion of use descriptions into the joint registration needs organisation of updating process in the consortia. DU upstream communication on uses is likely to pose confidentiality issues and is hardly enforceable. Only a direct use reporting by the DUs to the authorities would circumvent any such CBI issues. In addition. Reporting to authorities will generate much data but access to companies and data management will also cause high efforts.

**Interlinks with other options:** options are interrelated within this category of information

**Initial evaluation:** technical optimisations useful, inclusion in the impact assessment; change of CSR structure possible but almost the same result could be achieved by option A3.1.3; therefore, this option is not included in the impact assessment; DU requirements and joint registration discussed above (Sections A3.1.4, A3.1.6 and A3.1.7)

• Legal: no contradiction with existing law
• Information availability: should partly be available; better use descriptors would clarify understanding the PCs/ACs and granularity might increase in some instances
• Practicability: clarifications for all sides, supports implementation in general
• Alignment with policies: neutral

**A3.2.5 Information on the use process (worker and environment)**

The use description includes the specification of environmental release categories (ERCs) and process categories (PROCs), which integrate a rough exposure indication per default. However, the categories are broad and it is unclear to what extent they are correctly assigned by the registrants.

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197 Requires change of CLP regulation due to limited possibilities to use PCN information
**Optimization of IUCLID (incl. TCC), CSR and guidance**

- A review of ECHA’s R.12 guidance regarding the ERCs and PROCs could be considered to improve their understandability (ensure registrants more consistently select PROCs and ERCs) and more closely relate them to an expected exposure potential.
- Develop a structured field in IUCLID to enable entering / transferring from IUCLID exposure drivers, such as the operating temperature or water contact during use (cf. also Sub-Section A3.4.2).

**Implications**

**Target processes:** ARN, restriction

**Specific challenges (other than resource needs):** -

**Interlinks with other options:** Registrants usually do not know the CoU other than for their own uses, which is one of the reasons why ERCs and standardised exposure assessment tools were developed. Therefore, they may not be able to provide information on exposure determinants.

**Initial evaluation: useful and simple, inclusion in the impact assessment**

- Legal: no contradiction with existing law
- Information availability: applied in the CSR
- Practicability: clarification for all sides, supports implementation in general
- Alignment with policies: neutral

**A3.2.6 Information on the number of workers and sites applying a substance; number of potentially exposed consumers**

Information on the number of workers potentially exposed to a substance and the number of sites within which a substance is applied is useful in case a substance is only/mainly used in industrial uses. In these cases, an assessment of regulatory options may conclude that e.g. regulatory controls under OSH and installation related legislation may be sufficient to address the potential risk. Here, information on the number of sites applying a substance and the number of workers potentially exposed are currently missing.

The number of potentially exposed consumers is an important exposure proxy that helps the assessment of regulatory needs, the identification of the appropriate regulatory instruments and developing restriction proposals.

**Change of registration requirements**

- Make reporting of the number of exposed workers and the sites using a substance mandatory in the registration dossier
- Make reporting of the number of potentially exposed consumers obligatory

**Change of DU requirements**

- Oblige DUs to report upon request by their supplier (triggered by a request of the authorities) to them: the number of workers that a) is potentially exposed to the substance, i.e. all workers in the production or b) handles the specific hazardous substance
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- Oblige DUs to report to the authorities upon request the number of workers that a) are potentially exposed to the substance, i.e. all workers in the production or b) handle the specific hazardous substance\textsuperscript{198} and the number of sites at which they use the substance

**Other options:**

- Apply expert judgement: Estimate number of exposed workers based on the total number of workers employed in the sectors specified in the use description and expert judgement on the type of use processes the substance is applied in, which may give an indication of which share of the workers could be handling the substance\textsuperscript{199}
- Apply expert judgement: Estimate number of sites based on use descriptors (SU) and statistics. This may be linked to a general use reporting where the installations could be mapped\textsuperscript{200} (cf. Sub-Section A3.1.7).
- Enable ECHA to request information on the number of exposed workers and sites applying a substance during dossier evaluation (e.g. change REACH Art. 4.3)

**Implications**

**Target processes:** ARN, restriction

**Specific challenges (other than resource needs):** Information on the number of exposed workers and the sites applying a substance is generally not available. There is currently no statistics specifying the number of sites per sector. Hence, it must be generated by ‘counting’ the users and the exposed workers. Any related reporting obligation via the supply chain or immediately to the authorities are hardly enforceable. As this information would not improve the registrants’ CSR, a mechanism via the supply chain appears not senseful.

The information basis on sites for estimates, e.g. from the European Pollutant Release and Transfer Register (EPRTR) is rough and the reporting installation types are not differentiated according the Sus under REACH.

A change of registration requirements is disproportionate, as the information is relevant for only some registered substances. Therefore, either a DU reporting obligation (on request of the authorities) or the current approach of applying expert judgement appears to be appropriate.

**Interlinks with other options:**

- Initial evaluation: DU upstream communication covered under Section A3.1.6 and A3.1.7; registration requirements: not implementable --\textgreater\textemdash no further assessment; use of additional information sources --\textgreater\textemdash standing practice for drafting restriction proposals; no inclusion in impact assessment
  - Legal: no contradiction with existing law

\textsuperscript{198} This option would only work if authorities knew which companies use a particular (hazardous) substance, i.e. based on a DU use reporting

\textsuperscript{199} This could be estimated according to the method described in Annex of the Study EU Commission (2016): Study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Final report. Available at: https://ec.europa.eu/social/main.jsp?catId=716&langId=en

\textsuperscript{200} The current reporting under the E-PRTR is not considered suitable as there are reporting thresholds and many installations are therefore not covered. Whether the national company registers might be an information source could not be explored in the scope of this study.
• Information availability: not available to registrants, available for the own use at DUs, not available for consumer exposures
• Practicability: none of the options appears implementable except DU reporting to authorities and the use of existing information sources
• Alignment with policies: neutral

A3.2.7 Information on the legal coverage of substances/uses

Mainly for the assessment of regulatory needs but also for drafting restriction proposals, information whether the risks from (some) uses of a substance are adequately addressed under other legislation and which regulatory procedures under REACH are not applicable (e.g. intermediates) are important. Legal coverage mainly concerns identifying uses, which are subject to specific chemicals legislation, such as a use

a) As active substance in biocides, plant protection or medicines, where product approval systems ensure control of risks
b) In cosmetics, which would ensure control of health risks
c) Which is restricted according to REACH Annex XVII (which should be known to the ECHA)
d) Which is restricted under product specific legislation, such as Toy Safety, RoHS, the ELV, the Packaging Directive etc
e) Which requires authorisation

The current use descriptors do already reflect the current legal structure (ACs) and with the EUCLEF, ECHA has access to further information on the regulatory status of a substance. Registrants may not be sufficiently aware of the specific uses of a substance to indicate with certainty whether the end product are covered by legislation.

The ECHA is not necessarily aware of all product-related legislation and any ongoing risk management processes under other regulatory regimes. The lack of knowledge may increase with the sustainable products initiative, where chemicals are likely to be included and additional restrictions may be passed, or it may decrease as better information transfers between legislation are included in the new policy developments. Additionally, ECHA is not necessarily aware of any national requirements.

When restriction proposals are drafted, a detailed assessment of existing legislation is performed which may be based on registration information but is more likely to involve additional assessments.

Change of registration requirements

Require indicating the existing of an EU binding or indicative occupational exposure limit value and/or a national exposure limit value (create respective IUCLID field).

Change of DU requirements

DUs must inform the registrant about successful applications for authorisation so they can include the respective use(s) in the registration as identified use with an indication of the authorisation need (cf. above).

Other options:

Make better/more use of existing databases, such as EUCLEF, active substances in biocides and PPPs, on cosmetics ingredients, food and food packaging additives to confirm / verify uses and regulatory coverage
Implications

Target processes: ARN, prioritisation of SVHC for Annex XIV, restriction

Specific challenges (other than resource needs): registrants insufficiently aware of end-uses to specify legal coverage

Interlinks with other options: design of picklists (PCs, ACs)

Initial evaluation: none of the options seems feasible and useful --> no further assessment

- Legal: no contradiction with existing law
- Information availability: OELs should be available to registrants as they must indicate them in the safety data sheets, information on ongoing regulatory processes are more likely available at DU level
- Practicability: due to a lack of a central repository of OELs, integration of that information in the registration may lead to inconsistent information between and within registration dossiers, the information can be researched also by the authorities, if necessary. Informing about successful authorisations is not enforceable and registrants may check this on ECHA’s website
- Alignment with policies: might increase awareness of regulation on all sides, which would be in line with the aims of the CSS and other EU policies

A3.2.8 Ensuring consistency of information on the use pattern

- Integrate plausibility checks between information on the LCSs, the occurrence of an intended transformation (cf. Section A3.2.2) and the identification of SUs/PCs/ACs
- Define standard use/service life names that must be used.

A3.3 Information on tonnages

A3.3.1 Information on the consumption volume of a substance

Information on the total EU consumption of a substance is a rough exposure proxy. At present, there are uncertainties regarding what tonnages registrants provide in the registration dossier (total EU market volume, own production volume, tonnage band) and what amounts the registrants immediately export.

Optimization of IUCLID (incl. TCC), CSR and guidance

Clarify that registrants must provide their own tonnage in the technical dossier.

Change of registration requirements

Make information on (average) tonnages obligatory that are a) immediately exported by the registrant and b) used as intermediates by the registrant (specify in Annex I or Art. 10) on a regular basis or upon request by the authorities, e.g. if this is considered decisive in the assessment of regulatory needs
**Change of DU requirements**

On a regular basis or upon specific request by the authorities, implement a DU reporting obligation to the authorities on the total average annual amounts of hazardous substances exported via a) mixtures or b) mixtures and articles as well as the amounts used as intermediates.

**Other options**

Align production statistics to make usable for market overviews in the context of chemicals legislation, e.g. increase and specify reporting obligations with regard to substances in mixtures.

**Implications**

**Target processes:** ARN, prioritisation of SVHC for Annex XIV, restriction, policy success monitoring

**Specific challenges (other than resource needs):** Regular reporting could be aligned to regular reporting to production statistics, however granularity according to substances appears not feasible. DU reporting of export amounts on request requires access to the DUs that actually purchase the substances as such or in mixtures.

**Interlinks with other options:** general use reporting by DUs to get access to substance users.

**Initial evaluation:** DU reporting covered under Section A3.1.7; registration requirements useful -> inclusion in the impact assessment

- Legal: no contradiction with existing law
- Information availability: tonnage data for own use/export/intermediates available to the registrants,
- Practicability: possible to implement
- Alignment with policies: neutral

**A3.3.2 Tonnage breakdown per (groups of) uses**

Information on the tonnage breakdown per (groups of) uses helps weighting the relevance of (critical) uses against others in the assessment of regulatory needs or the prioritisation of SVHCs for Annex XIV inclusion. It is important input data for demonstrating risks and making SEAs when drafting restriction proposals, as well as for the monitoring of policy success (reduction of critical uses).

Critical issues regarding the tonnage breakdown include inconsistencies of total tonnages vs. tonnages per use; lack of tonnages of uses covered by specific legislation, lack of up-to-date information. The purpose of the CSR of demonstrating safe use and the iterative chemical safety assessment process may prevent that realistic use amounts are reported (i.e. registrant stops assessment when safe use is demonstrated). Registrants lack detailed information on the tonnage breakdown according to the uses and the information basis for providing that information is not transparent to the authorities.

**Change of registration requirements**

- Make import of all tonnage information from the ESs obligatory, e.g. tonnage used to estimate environmental risks and tonnage ending up in consumer mixtures, including a justification / description how the tonnages were derived
- Make information on tonnages that is independent of the exposure assessment obligatory in the registration that is provided per each exposure scenario. Update guidance to explain why
additional tonnage information is requested and how it should be obtained (i.e. market intelligence)

- Explicitly require specific tonnages per PC and AC

**Change of DU requirements**

- Implement a reporting obligation of DUs to the registrants either a) regularly or b) on request of the registrants due to a dossier update, to provide the average tonnage of a substance used a) per received ES b) per PC (in relation to ACs),
- Implement a reporting obligation of DUs to provide the authorities with information on the tonnages used per a) ES received or b) PC (in relation to AC and/or SU). The reporting obligation could be a) on a regular basis (e.g. corresponding to potential dossier update deadlines), b) upon request of the authority (e.g. when starting a regulatory process)

**Implications**

**Target processes:** ARN, prioritisation of SVHC for Annex XIV, restriction, policy success monitoring

**Specific challenges (other than resource needs):** Registrants only know tonnages of their own markets. Tonnage information is a) considered confidential and b) subject to frequent changes. Therefore, DU use reporting up the supply chain is not an option. A use reporting to the authorities (on request) therefore is considered the only option that would significantly improve the information situation on tonnages per use.

**Interlinks with other options:** changes in the structure/possible content of an ES would influence the granularity of tonnage reporting

**Initial evaluation:** Import from Chesar covered under Section A3.1.2, change of DU requirements under Section A3.1.6 and A3.1.7; change in registration requirements under A3.1.3

**A3.3.3 Consistency of information**

**Technical options**

Enable information transfer (or manual entry) of information from the CSR to IUCLID about amounts per use and enable consistency checks. Highlight if total registration amount and total amount in all uses (as provided independent of the CSR) diverge significantly.

**A3.4 Information on CoU**

**A3.4.1 Information about how a substance is included in mixtures and articles**

Information on how a substance is included in products may serve as an exposure proxy. This information is generally provided in the exposure assessments but not always explicit (e.g. the matrix integration is only implicitly provided via environmental release factors), and they are not automatically included into IUCLID. As the CSR is designed to demonstrate safe use, the authorities consider the information not sufficiently reliable.
**Change of registration requirements**

Implement an explicit obligation/clarification in Annex I that the registrants must provide information on:

- The physical state of (each) mixture containing the substance,
- The average concentration ranges of a substance per PC and
- The (assumed) form of integration in matrices.

This information should be filled with information independent from the exposure assessment, i.e. could be across ESs but without worst case assumptions. Revise guidance documents, create missing IUCLID data fields and make information subject to TCC.

**Change of DU requirements:**

- Implement an upstream reporting obligation for DUs to a) regularly or b) on request of the registrants (justified by a regulatory request and forwarded down the supply chain) to provide information on the aggregate state of mixtures containing the substance (per (similar) PCs), the average concentration ranges in mixtures or articles (per PC/AC) and the (assumed) integration in matrices (per (similar) PCs and (groups of ACs in the same group of material types),
- Implement a reporting obligation of DUs to provide the authorities with information on the aggregate state of mixtures containing the substance (per (similar) PCs), average concentration ranges in the mixtures (per PC) and (assumed) integration in matrices (per (similar) PCs. This could be reported a) regularly (only changes) or b) upon request

**Other options**

- Integrate information from the PCN on the average concentrations in mixtures
- Make use of the Nordic Product Registers / SPIN

**Implications**

**Target processes:** ARN, restriction

**Specific challenges (other than resource needs):** Concentrations in mixtures are considered confidential, i.e. supply chain communication is hardly possible.

**Interlinks with other options:** link to overarching option to transfer the exposure assessment to the registration dossier; however, this option considers providing data that is based on market knowledge and not derived in the CSR. Due to the large number of mixtures and articles, the only workable option appears to be a reporting to the authorities on request.

**Initial evaluation:** DU communication covered under Section A3.1.6 and A3.1.7; registration requirements: feasible inclusion in impacts assessment, use of additional information sources is current practice; no inclusion in impact assessment

- Legal: no contradiction with existing law
- Information availability: registrants should have information on exposure proxies in CSRs; however not registrants that do not make a CSR.
- Practicability: generally feasible
- Alignment with policies: neutral
A3.4.2 Information on the operating conditions (OCs) and risk management measures (RMMs) during use and service life

Information on the OCs and RMMs are mainly used as input information for drafting restriction proposals. Exposure proxies (PROCs, ERCs as such) but potentially also additional information could be helpful for the ARN. Currently, in many cases PROCs and ERCs (SPERC) are used as provided by ECHA’s R.12 guidance document, which includes generic descriptions of the OCs and partly the RMMs.

Change of registration requirements

Require registrants to make the entire exposure assessment available from the CSR either via import from Chesar or via a manual information input (REACH Art. 111)

Change of DU requirements

- Require DUs to confirm to the registrant if their CoU correspond to those communicated in the ES or, if this is not the case, require them to report their CoU upstream, including on applied RMMs and respective efficiencies by changing REACH Art. 34.
- Require DUs to provide their DU CSR together with a DU CSR notification to ECHA
- Require DUs to report information on the CoU upon (specific) requests of the authorities, e.g. in the scope of a restriction proposal

Other options

- Integrate information from BREF documents (manual extraction of relevant information, potentially as part of a project) and derive state-of-the-art CoU at sites from them
- Compile information from consultations (restriction proposals, authorisation applications) on the state-of-the-art CoU at industrial sites, in professional uses and in articles

Implications

Target processes: restriction (ARN, policy success monitoring)

Specific challenges (other than resource needs): information on OCs and RMMs should be collected in a mechanism not linked to the registration dossiers to make it manageable and specific. As the information is not needed for most substances, a general reporting requirement is considered as disproportionate.

Interlinks with other options: -

Initial evaluation: DU communication covered under Section A3.1.6 and A3.1.7; registration requirements: covered under A3.1.2. Requirement to provide the DU CSR with the notification useful but considered to ‘minor’ -> no further assessment.201

- Legal: no contradiction with existing law,
- Information availability: the DU CSR is developed by the downstream user and must be available.
- Practicability: easy to implement, no efforts. If implementation via Chesar, more efforts may be needed on the side of the DUs

201 Although not being proposed for the impact assessment, the option could be implemented ‘in any case’ because the DU CSR must be available already under current legislation and attaching it to the notification is considered as ‘negligible effort’ but additional information would become available for the authorities.
• Alignment with policies: neutral

**A3.4.3 Information on waste treatment**

The treatment of wastes may considerably contribute to environmental emissions and to workers’ exposure to hazardous substances. Either aspect is to be considered both by the registrants and by the authorities in their assessment of regulatory needs and the implementation of regulatory actions, specifically restrictions.

**Optimization of IUCLID (incl. TCC), CSR and guidance**

- Include option (with picklist) to indicate likely type of waste processing of articles (if service life is relevant). Develop respective list of waste treatment operations with different exposure potentials, including recycling, e.g. based on BREFs and in conjunction with the efforts on an improved circular economy
- Integrate data fields to provide estimates of the release potential of a substance from an article during waste treatment on a voluntary basis.

**Change of registration requirements**

- Make the assessment of the waste stage of substances obligatory, independent of whether risks from the use and service life are assessed in the CSR. This obligation could be a) qualitative, i.e. mainly consisting of an indication of the treatment processes or b) quantitative, as described by ECHA’s guidance document on exposure assessment of the waste stage.
- Include a requirement for registrants to specify the total amount of a produced substance entering the waste stage per lifecycle stage

**Change of DU requirements**

Require DUs report the ACs into which they include the substance up the supply chain to enable the registrant deriving the relevant waste treatment processes

**Other options**

- Compile information from the waste treatment sector on the CoU and their influence on emissions to the environment to improve / update the guidance document on exposure assessment of the waste stage.
- Check the CSR regarding the content of an assessment of the waste stage

**Implications**

**Target processes**: restriction (ARN)

**Specific challenges (other than resource needs)**: The core challenge for the registrants is to know which products their substances are included into, as this will determine the type of waste treatment the most. This means that use pattern information is decisive for the improvement of registration data. Emission and exposure models from the waste treatment sectors are currently missing (other than those included in the ECHA guidance) and their development may be useful, also for other processes, e.g. in the context of closing material cycles without recycling hazardous substances.
**Interlinks with other options:** updating can be implemented independent of other options but the extent of the update is determined by which other (additional) options are implemented.

**Initial evaluation:** DU communication covered under Section A3.1.6 and A3.1.7; registration requirements: considered too little discussed and unclear with regard to the needs and benefits; therefore, no further assessment.

- Legal: no contradiction with existing law, gap and overlap with waste legislation exists
- Information availability: registrants lack information on the type of waste processing their substance is likely to enter
- Practicability: would require conceptual work for developing tools and guidance for registrants to implement waste related assessments in their registration dossier
- Alignment with policies: could support policy integration with waste legislation and enhance the circular economy goals.

### A3.5 Information on emissions

#### A3.5.1 Migration and release rates from matrices

Migration and release rates from matrices (used in articles) can qualify the exposure potential. It is relevant for demonstrating risks when drafting restriction proposals. This information is not normally provided in registration dossiers and is available only for a small number of substances, e.g. additives used in plastics for use in food contact materials.

**Optimization of IUCLID (incl. TCC), CSR and guidance**

- Integrate data fields in IUCLID to provide on a voluntary basis modelled or measured migration rates of substances from relevant materials (e.g. plastics, glass, paper etc.) as derived from the indicated ACs (consistency checks)
- Review ERCs and assess if how they could be differentiated, e.g. according to more specific evaporation or leaching rates or considering specific exposure determinants (more), such as water contact or abrasion in particular for the ERCs covering service life

**Change of registration requirements**

Require registrants to provide measured or modelled migration/release rates from materials relevant to the specified ACs (beyond generic release rates in ESs) a) in registration dossiers or b) upon request by the authorities

**Change of DU requirements**

Require DUs to provide migrations rates of substances they use in their mixtures / articles to the authorities on request

**Other options:**

Explore how migration models can be provided to the market actors to determine migration rates

**Implications**

**Target processes:** restriction, (ARN)
Specific challenges (other than resource needs): many combinations of substances and material possible, limited number of migration models exist

Interlinks with other options: -

Initial evaluation: options requiring registrants to provide specific information unrealistic due to lack of (access to) data --> no further assessment; options for DU reporting to the authorities included in impact assessment.

- Legal: no contradiction with existing laws
- Information availability: DUs may not have the information but have good preconditions for generating it. Models may be available as well as standardised measurement methods (e.g. chamber testing for construction materials).
- Practicability: requires access of the authorities to the DUs applying a substance to make targeted request (c.f. general DU reporting)
- Alignment with policies: may create synergies with other legislation. Increases awareness on chemical emissions and risks

A3.5.2 Quantified releases to the environment

Change of registration requirements:

Make provision of total releases to the environment (per emission pathway) obligatory in IUCLID (separate field subject to the TCC, either filled via transfer from Chesar or manually)

Change of DU requirements:

- Require DUs to communicate information on the amounts emitted from their own use upstream a) upon request b) regularly
- Require DUs to report information on released amounts upon (specific) requests of the authorities, e.g. in the scope of a restriction proposal

Other options:

- Use additional information sources about measured environmental releases (e.g. European Industrial Emissions Portal)
- Work with generic assessments

Implications

Target processes: restriction

Specific challenges (other than resource needs): information measured emissions and specific release factors from processes are not normally available

Interlinks with other options: access to DUs for specific requests needed, e.g. via generic use reporting

Initial evaluation: options requiring registrants to provide specific information unrealistic due to lack of (access to) data --> no further assessment; options for DU reporting to the authorities included in impact assessment.

- Legal: no contradiction with existing laws
• Information availability: DUs may not have the information but have good preconditions for generating it. Models may be available to quantified environmental emissions at site as well as measured data (e.g. concentrations in the waste water) or could be generated on request.
• Practicability: requires access of the authorities to the DUs applying a substance to make targeted request (cf. general DU reporting)
• Alignment with policies: may create synergies with other legislation. Increases awareness on chemical emissions and risks

A3.6 Information on exposures of humans and the environment

Optimization of IUCLID (incl. TCC), CSR and guidance

Assess PROCs regarding a) opportunities to link them to generic exposure levels (i.e. high, medium, low) or b) options to derive exposure levels at the workplace for more realistic exposure assessments

Change of registration requirements

Make reporting of the entire exposure assessment in IUCLID subject to the TCC (i.e. automatic import from Chesar or manual inclusion is the use of Chesar is not mandatory)

Change of DU requirements

Require DUs to report information on modelled or measured exposures upon (specific) requests of the authorities, e.g. in the scope of a restriction proposal

Other options:

Improve the accessibility of exposure information from databases, i.e. IPChem

Implications

Target processes: restriction, policy success monitoring

Specific challenges (other than resource needs): lack of (bio)monitoring data for most substances, exposure information from the workplace risk assessment should be available at least for some substances and from some sites

Interlinks with other options: access to companies needed to make information requests by the authorities

Initial evaluation: options requiring registrants to provide specific information unrealistic due to lack of (access to) data --> no further assessment; options for DU reporting to the authorities included in impact assessment.

• Legal: no contradiction with existing laws
• Information availability: Data from workplaces may be available as well as from modelling consumer and environmental exposure based on more specific input information as used by the registrants in the CSR. Environmental exposure data or information on the human exposure of the public is not available to the DUs other than from public databases.
• Practicability: requires access of the authorities to the DUs applying a substance to make targeted request (c.f. general DU reporting)
• Alignment with policies: may create synergies with other legislation. Increases awareness on chemical exposures and risks

A3.7 More granular information on use patterns, tonnages, CoU, emissions and exposures for drafting restriction proposals

Several types of information are needed in addition to or at a higher granularity than for the other regulatory processed to support scoping and justifying restriction proposals, including information on:

• type of transformation products
• (degree of) process containment
• tonnage breakdown per specific use (i.e. higher granularity than PCs/ACs)
• tonnage of end-products on the market
• tonnage used by individual users

This type of information could be gathered from literature and databases or from the market actors. While the former would mainly depend on the availability of (detailed) statistics and the available expertise of the persons making the restriction proposal, any information gathering from the market actors depends on the access to these actors and their motivation to respond to the authorities’ requests. Once an access is there, in principle any information could be asked for.

As the information needs are diverse, may be very specific and applicable to a small sub-set of all registered substances, no options are provided here ‘per information item’ in addition to the options before. Two approaches, which are generic, but would both cover all potential information needs are provided in Section 1.