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EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on Information Requirements and Chemical Safety Assessment

Chapter R.12: Use description

Version 3.0
December 2015

LEGAL NOTE

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Guidance on Information Requirements and Chemical Safety Assessment
Chapter R.12: Use description

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Preface

This document describes the information requirements under the REACH Regulation with regard to substance properties, exposure, use and risk management measures, and the chemical safety assessment. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH Regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under the REACH Regulation.

The original versions of the guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. After acceptance by the Member States competent authorities the guidance documents had been handed over to ECHA for publication and further maintenance. Any updates of the guidance are drafted by ECHA and are then subject to a consultation procedure, involving stakeholders from Member States, industry and non-governmental organisations. For details of the consultation procedure, please see:

http://echa.europa.eu/documents/10162/13559/mb_63_2013_consultation_procedure_for_guidance_revision_2_en.pdf

The guidance documents can be obtained via the website of the European Chemicals Agency at:

http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1].

1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p.1; corrected by OJ L 136, 29.5.2007, p.3).

Document History

Version	Changes	Date
Version 1	First edition	May 2008
Version 1.1	• The process categories (PROC) related to processing of metals and other minerals were included into the PROC numbering system • SU 10 has been slightly re-phrased • "PC 39, personal care products" have been added • Pulp has been added in SU 6 and a subdivision has been made related to "other" production or services (0-1 for "other economic activities related to chemicals" and 0-2 for "other economic activities, not related to chemicals") • The numbering system of the article categories has been technically streamlined • All "other" has been moved from the last position in the pick-list to the first position	July 2008
Version 1.2	• Correction of numbering from PROC 22 in Appendix R.12-3. • Moving the misplaced cameras and video cameras from AC 9 to AC 3-4 in Appendix R.12-4. • Adaptation of the numbering system in Appendix R.12-4 to the structure of the categories.	October 2008

Version 2	• Improving clarity and consistency of the introduction with regard to the purpose of the use descriptor system.
	• Making more explicit references to Article 37 (DU makes use known to supplier) and section 3.5 of IUCLID in section R.12.1
	• Inclusion of clarifications and definitions in R.12.2
	  • Streamlining the terminology regarding "chemical products" (= substances as such and in mixtures) and articles
	  • Dried/cured mixtures are covered by Article Categories since they have a defined shape and surface.
	• Inclusion of updated examples on how to work with the descriptor system: See Section R.12.4 and R.12.5.
	• Introduction of a new table R.12.1 in order to better explain the relationship between use description and Tier 1 exposure estimates.
	• Adding a short paragraph in section 12.2.1 regarding the different actors in the life cycle of a substance.
	• Harmonisation of the structure of section 12.3.1 to 12.3.5. Inclusion of 3 subsections: definition and scope of the descriptor; guidance on assigning a suitable category; link to Tier 1 assessment.
	• Splitting of the Sector of Use descriptor list into two types of information: Main User Groups in the life cycle of a substance as key descriptor (SU 3, 21, 22) and Sector of End-Use (all entries) as supplementary descriptor, see Appendix R.12-1.
		March 2010

	• More clearly distinguishing of the two functions of the Chemical Product Category (PC) in section R.12.3.2: (i) describing the sectors formulating mixtures by mixture type and (ii) consumer product types that can be assessed with the ECETOC Targeted Risk Assessment for consumers (see Appendix R.12-2.2).
	• More clearly distinguishing between the two functions of the Article Category (AC) in section 12.3.5: (i) Type of article related to service life and subsequent waste life stage of the substance (handling of article by workers and/or consumers) and (ii) consumer article types that can be assessed with the TRA. See Appendix R.12-5.1 and R.12-5.3.
	• Inclusion of a list of product sub-categories addressed in the ECETOC Targeted Risk Assessment (TRA) for Consumers, see Appendix R.12-2.2 and Appendix R.12-5.3, Explaining the link between use description and Tier 1 exposure estimates in section R.12.3.2 and R.12.3.5.
	• Removal of the reference to industrial or professional setting from most of the process categories. The choice can be made in the exposure estimation itself. At use description level, SU 3 or SU 22 indicate, whether a use is expected to occur under an industrial or non industrial setting.
	• Inclusion of examples related to processing of articles by workers into section R.12.3.5. Restructuring of the AC list to allow consistent links to the TARIC system. Removal of definitive sub-categories in the AC list in order to leave it to the registrant and the downstream users to define the level of detail required to describe the service life stage of the substance. The previous subcategories have been converted into examples illustrating which kind of articles may be covered under the broad categories.
	• Introduction of the Environmental Release Category (ERC) as an additional descriptor (see section R.12.3.4). Explanation on the role of SPERCs in this context.
	• Introduction of a new category ERC 12 addressing processing of articles with abrasive techniques by workers in industrial setting. Expanding ERC 10b/11b to also cover removal of substances from article surfaces.
	• Inclusion of a list of substance function categories (for section 1.2 of the extended SDS and reporting in IUCLID) in Appendix R.12-6. The purpose of this list is explained in a short paragraph in section R.12.3.6
	• Introduction of a new section R.12.5 with explanation of how the descriptor system can support i) the mapping of uses as the starting point for the CSA, ii) the building of titles for exposure scenarios and iii) the reporting on identified uses in IUCLID section 3.5.
	• Refinements in the pick-lists:
	  • Include i) scientific research and ii) electricity, steam, gas, water supply and sewage treatment into the SU list.
	  • Split out fillers and putties from PC 9 into PC 9b
	  • Split out finger paint from PC 9 into PC 9c.
	  • Clarification that PC14 refers to substances reacting with the metal surface
	  • Remove automotive care products (PC6), artist's supplies (PC5), lawn and garden products (PC22) since it largely duplicates other categories
	  • Remove PC10 since this is covered under "others"	

	anyway • Clarification that PC20 refers to processing aids used in the chemical industry • Inclusion of bleaches and other processing aids into PC 26 and PC 34 • Covering metals and other minerals in PROC 21 to 25 plus adaptation of description • Splitting PROC 8 into PROC 8a and 8b • Introduction of PROC 26 and 27a and 27b referring to processes particularly relevant for the metal industry • Remove AC12 from the AC list since it leads to major inconsistencies with the material based categorisation and creates problems in compatibility with the TARIC system. • Editorial adaptation of the text to the changes listed above.	
Version 3.0	• Guidance scope extended to 'Use description' (rather than only 'use descriptor system') and title adjusted to reflect this • Explanation of the role of use information in various processes • Clarification of some terms/concepts/requirement such as: o Concept of use / contributing activities o Scope of Life cycle stages including differentiation industrial/professional o Obligation to include use information in the registration dossiers • List of use descriptors: o New use descriptor: Life cycle stage replacing main user groups SU 3 (industrial uses), 21 (consumer uses), 22 (Professional uses), 10 (Formulation) o Life-cycle stage 'Formulation' renamed 'Formulation or re-packing' to make clear its scope o 'Professional uses' renamed into 'Widespread uses by professional workers' to clarify the fact that these uses are considered as widespread from the environment point of view. o Main user groups removed from SUs as covered by new use descriptor 'Life cycle stage' o Removed PC19: intermediate (covered by Technical function) o Shorter names for PCs o New PC for hydraulic fracturing o New PC for electrolytes for batteries o PROCs names and explanations adapted to clarify their scope o New PROC for cleaning and maintenance (PROC28) o Clarification of applicability of ERCs by adapting names and explanations o New ERC to cover the use of articles at industrial sites with low release o Enhancing the concept of AC sub-categories to bring more specific information on articles o Adaptation of categories for Technical functions and Article categories to align with the OECD process for globally harmonised categories	December 2015

	• New Appendix added (Appendix R.12-5) to explain how to manage the changes introduces by this update of the guidance.	

Convention for citing the REACH regulation

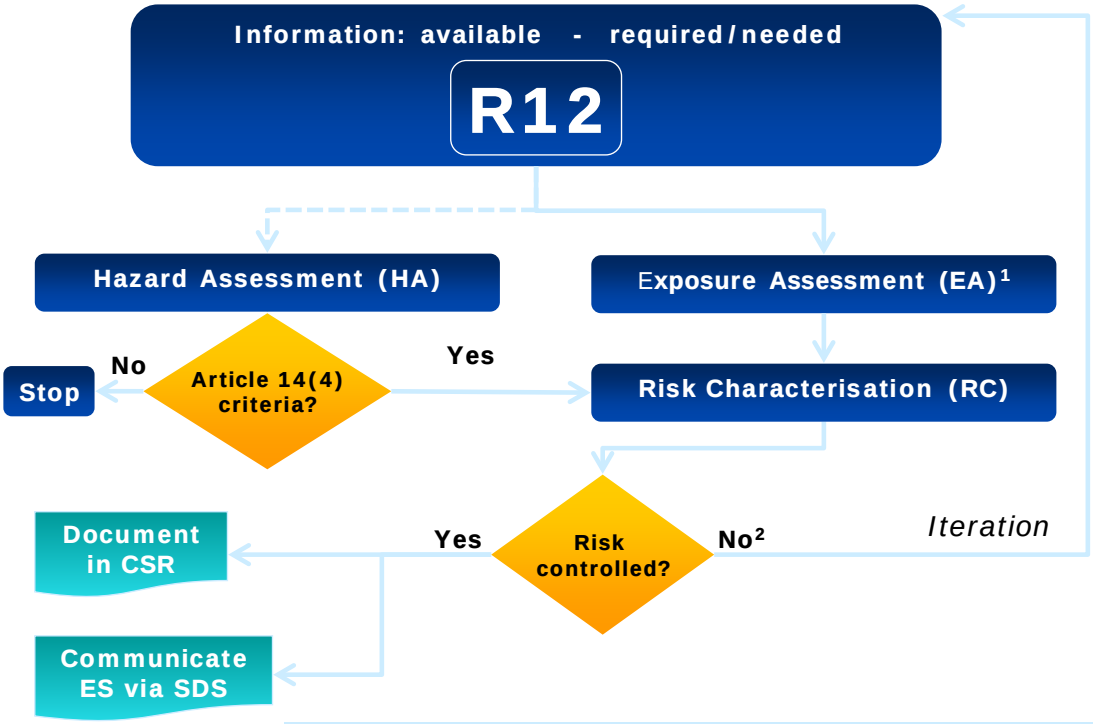
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20

Pathfinder

The figure below indicates the location of chapter R.12 within the Guidance Document



[1] Assessment acc. to REACH Annex I is only required if substance meets the criteria for any of the Article 14(4) hazard classes, categories or properties, or exposure based waiving to be applied (Annex XI)

[2] It is also possible that the outcome of the assessment is to list the use as advice against (to be reported in the SDS)

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R.12.1. Introduction

R.12.1.1. Aim of this guidance

The aim of this guidance is to explain the role of use-information for the various REACH processes, to explain the related legal requirements and to set out the principles for describing the uses of chemical substances.

Under REACH each manufacturer and importer of a substance is obliged to provide a brief general description of the identified uses in his registration dossier. A use in this context means any utilisation of a substance as such or in a mixture[2]. This includes for example: formulation of mixtures, or production of an article[3]. This Guidance clarifies what this brief general description of the identified uses entails[4] to ensure it is fit for purpose.

The description of uses is a key pre-requisite for the registrant's safety assessment (where required) and the subsequent communication of the conditions of safe use down the supply chain. The description of identified uses is also meant to enable the authorities to understand what is practically done with a substance in the market. This supports well informed decisions on what priority the substance has for further scrutiny and regulatory action(s) by authorities. In addition, some of the information on uses from the registration dossiers is disseminated via the ECHA website to the general public. This enables the general public to have indications on products or articles where substance can be present, as well as processes and sectors that make use of a given substance. And last, the description of uses also plays an important role for Downstream users particularly in the verification of whether their uses are covered in the exposure scenarios communicated to them.

Therefore it is important for all REACH actors (registrants and downstream users, authorities and the public at large) to have a common understanding on what the use description in the registration dossier is and what it should contain to best serve its purposes.

R.12.1.2. Who should read this guidance?

The main focus of the guidance is the use description in the context of REACH Registration, although the role of the use description in other REACH processes such as dissemination is also addressed in this document. The description of uses in the context of the application for authorisation is addressed in the ECHA document "How to develop the description of uses in the context of Authorisation" available on http://echa.europa.eu/web/guest/applying-for-authorisation.

This guidance addresses registrants and downstream users as both groups of actors need to communicate with each other to arrive at a meaningful description of uses in the registration dossier and in the extended safety data sheets. Downstream users can also make use of the principles in this guidance in the context of a downstream user report according to Article 38 of REACH.

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[2] Article 3(24) of the REACH legal text includes a definition of use: " *use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation*".

[3] Article 3(3) of REACH provides that "*article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*"

[4] Concrete fields are provided by the IUCLID format, particularly section 3 on use information.

Authorities also deal with use information from registrations (e.g. substance evaluation). Therefore, they could also benefit from reading this guidance.

R.12.2. Use description as legal requirement

According to REACH, Registrants are required to provide a "*brief general description of the identified use(s)*" in the technical dossier for all substances for which registration is required (Article 10(a)(iii) and Annex VI, point 3.5 REACH).

This requirement 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 to. It applies to all types of substances (classified/non-classified) and all tonnage bands (including 1-10 t/y).

It should be noted that where substances have been previously notified under 67/548/EEC and where the tonnage band and uses have remained the same as the ones notified, the company is not explicitly required to comply with Annex VI of REACH, but including a description of uses is highly recommended.

Where registrants are required to carry out an exposure assessment in the context of the Chemical Safety Assessment (CSA), consistency between the brief description of the uses in the technical dossier and the exposure scenarios (ES) in the CSR is required (see section 5.1.1 of REACH Annex I). A number of elements for describing uses have been defined in IUCLID to support this consistency requirement. In the exposure assessment the manufacture, all the uses of the substance (on its own, in a mixture) and the subsequent life-cycle stages (article service life and waste stage) are to be addressed. Safe use should be demonstrated for each use reported.

The description of uses as reported in the registration dossier should therefore provide an appropriate level of information to allow understanding of what is done with the substance, in particular to support a meaningful exposure assessment of the uses. The use description includes therefore any use of the substance as such and in mixtures and any subsequent service life[5] in articles resulting from a use. Although manufacture is not a use, it should also be described. The waste stage is not part of the use description.

Use reporting also plays a role for substances with no exposure assessment obligation. Substances manufactured/imported between 1-10 t/y give rise to registration obligations but no exposure assessment has to be performed. Substances manufactured/imported in quantities > 10 t/y, but not meeting the criteria set out in Article 14(4) REACH[6] also do not need to undergo an exposure assessment. Nevertheless, in both cases, registrants have the obligation to include a brief general description of the identified use(s) in the registration dossiers (Annex VI 3.5). In order to do so, they are advised to follow the elements described in this guidance and implemented in IUCLID.

Registrants should also take into account that the obligation to submit in the technical dossier 'all information available to the registrant' applies. For example if the registrant is in possession of descriptions of uses from the joint submission.

In cases where the registrant has used use information for adaptation of the information requirements based on exposure/release considerations, or for selecting an appropriate route of administration according to REACH Annex VII-X column 2, use information (as well as corresponding exposure information) should be consistent with the justification of the

[5] Service life means the period of time an article remains in service or in use.

[6] Please note that in the rest of the Guidance, these criteria will be referred to by using the term "hazardous".

adaptation; for example, where the registrant wishes to waive higher tier human health end-points based on strictly controlled conditions (REACH Annex XI 3.2, and more specifically for substances incorporated into articles Annex XI 3.2(c)).

Where information gaps impact on the ability to establish whether or not a classification criterion is met, the registrant should detail his use description to the extent that would be appropriate for a substance considered to be hazardous.

In the case of intermediates, as for other substances, a description of the use needs to be provided in the registration. Information included in registration dossiers on the use as intermediate such as the share of the total tonnage for that use are particularly relevant for authorities when substances are to be selected and prioritised for further regulatory actions (e.g. inclusion in the authorisation list, restrictions etc.) and when deciding on the best regulatory risk management option.

If a registrant fails to report information on uses without valid justification, he can be requested to provide such information in the context of compliance check.

It should be noted that members of joint registrations have to provide a brief description of uses and cannot simply refer to the dossier of the lead registrant, even if the CSR has been submitted jointly. According to Article 11, each registrant must submit separately the information specified in Article 10(a)(iii) i.e. the information on the manufacture and uses(s) of the substance. The information provided should represent the uses of the registrant and of his own supply chain.

R.12.3. Role of the use description in different processes

The use description plays an important role for many different actors, including:

- Registrant's requirement to perform a chemical safety assessment. Registrants who are required to carry out an exposure assessment in the context of the Chemical Safety Assessment (CSA) have to address all identified uses of the substance and to report the outcome of the chemical safety assessment in their Chemical Safety Report (CSR).

- Suppliers of hazardous substances or mixtures that have to provide the recipient with a safety data sheet (SDS) according to Article 31. The SDS has to include use information.

- Downstream user's (DU) obligations: DUs can communicate their use to suppliers. They also have to check whether their use is covered by the exposure scenario they receive. In case they carry out their own CSR, the brief description of the use is part of the information to be reported to ECHA.

- Authorities' tasks include the selection and prioritisation of substances for further regulatory processing e.g. Substance Evaluation, identification of Substances of Very High Concern (SVHC), Restriction, etc. The authorities' screening and prioritisation considers the use of the substance (e.g. wide-disperse characteristic of the use of the substance). Enforcement authorities also rely on information on uses to verify the implementation of the exposure scenario.

- General public's access to information on the use of chemicals: non confidential information on uses is disseminated.

It is therefore important to understand the purpose of the use description in order to better understand the necessary information to be collected and reported. The role of the use description in different processes is further detailed below.

R.12.3.1. Use description as part of the registration dossier and as a basis for the exposure assessment

Registrants who are required to carry out an exposure assessment in the context of the Chemical Safety Assessment (CSA) have to address all the uses of the substance of the registrant and its supply chain in the EU (as such, in a mixture or in articles) that they are aware of and to report the outcome of the chemical safety assessment in their Chemical Safety Report (CSR). The use description plays a crucial role in this process as it is the basis to ensure a meaningful and complete exposure assessment. The CSR for hazardous substances includes exposure scenarios that define the conditions of use that ensure control of risks associated with the uses of the substance throughout the life-cycle of the substance.

As a first step of the assessment, registrants need to identify all the uses of their substances including realistic information on the corresponding conditions of use. An efficient way for a registrant to get such information is to retrieve it from *use maps* developed by suppliers or Downstream user sector associations[7]. *Use maps* provide a sector-harmonised description of the main uses relevant for the sectors and information on conditions of use that are typical in the sector and could be used as input for their registrations in particular the chemical safety assessments. Such a mapping of uses within a market sector can be reused for a range of substances ending up in that market.

More information on use maps can be found in the action area 2 of the CSR/ES Roadmap website: http://echa.europa.eu/csr-es-roadmap

The uses covered in a registration are to be included in the technical dossier. The dossier is compiled and submitted in a IUCLID format. A specific section is designed to include the use information for the various life cycle stages relevant for the substance.

Exposure scenarios are then generated for each use by the registrant while performing the CSA. The exposure scenarios in the CSR and the identified uses described in the technical dossier have to be consistent. They should also be consistent with the exposure scenarios that are later on communicated to downstream users in the supply chain (as an annex to the safety data sheet (SDS)).

R.12.3.2. Use description for communication on safe use down the supply chain

Relevant identified uses and uses advised against are also to be listed in section 1.2 of the SDS. Where a CSR is required, the information in this subsection of the SDS must be consistent with the identified uses in the CSR and the exposure scenarios set out in the annex(es) to the SDS.

It is generally good practice to include a table of contents before the annexed ESs in the extended-SDS. This table of contents is composed of the short titles for communication which should give a first indication to the recipient on which ESs are applicable to his use. The ES also includes a title section where a more detailed description of the activities covered by the ES is provided. Both ES titles (included in the ES to give an overview of the scope) and short titles for communication (included in the table of content and the ES to facilitate the sorting of the different ES) need to be consistent with the information on use in the registration dossier.

More information on short titles can be found under action 2.5 of the CSR/ES Roadmap:

[7] Use maps can even be collectively created by several manufacturers/importers in dialogue with downstream sectors.

http://echa.europa.eu/csr-es-roadmap and in the Appendix R.12.1.

Downstream users receiving extended-SDSs should check the content of the exposure scenario(s) describing their uses to ensure that their conditions of uses are covered and the risk management measures implemented. An appropriate description of the scope of the use is also key in this process to make sure that DUs recognise their uses and can process the information on safe use communicated in the supply chain.

R.12.3.3. Use description as a basis for authorities' decision making

REACH is set up so that authorities can identify whether or not further scrutiny or regulatory actions are needed for some chemicals.

The REACH registration database contains a high number of substances potentially of concern considering i) their known hazard profile and/or ii) existing data gaps. Authorities need to concentrate their action by defining priorities among the substances, as well as assessing the compliance of the exposure assessments carried out by the registrants. Selection of substances for further scrutiny, compliance and prioritisation for further regulatory actions, is to a certain extent based on information on uses provided in the registration dossiers[8]. Therefore, the description of uses is to be transparent and complete. Where ES are required, uses must be unequivocally linked to the exposure scenario in which the conditions for safe use are described. Once a substance has been prioritised for further risk management measures, the quality of the use description might also impact on the decision by authorities on the most adequate risk management option. A clear picture on the use pattern of a substance supports authorities in deciding on actions. As an example, if industry demonstrates that a given substance is not used in a wide-dispersive manner, and/or it has low tonnage for uses that might fall within the scope of authorisation, this substance will get lower priority during the entire selection and prioritisation process (that may at the end lead to inclusion in Annex XIV). To enable authorities to assess substances against prioritisation criteria, the relevant information on uses (and conditions of use) should be provided as part of the registration dossier. In addition to being available, the authorities need this information to be structured in a way that supports comparison among substances and dossiers and allows (IT)-processability. The provision of the registration dossiers in the IUCLID format allows such IT processability. It is important to realise that in the absence of sufficient and consistent information on uses, worst-case assumptions may have to be made during the scrutiny phase. This may hamper the efficiency of regulatory risk management (substances get selected for further scrutiny and action due to wrong reasons).

R.12.3.4. Use description for dissemination of information to the general public on the use of chemicals

Information on uses (identified uses and uses advised against) is disseminated on the ECHA website[9] for public information on the registered substances. Therefore the reporting of meaningful and clear use names[10] and relevant use descriptors[11] is of high relevance to at

[8] Further information on selection and prioritisation of substances of potential concern can be found on ECHA website

http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/screening

http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list

[9] http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

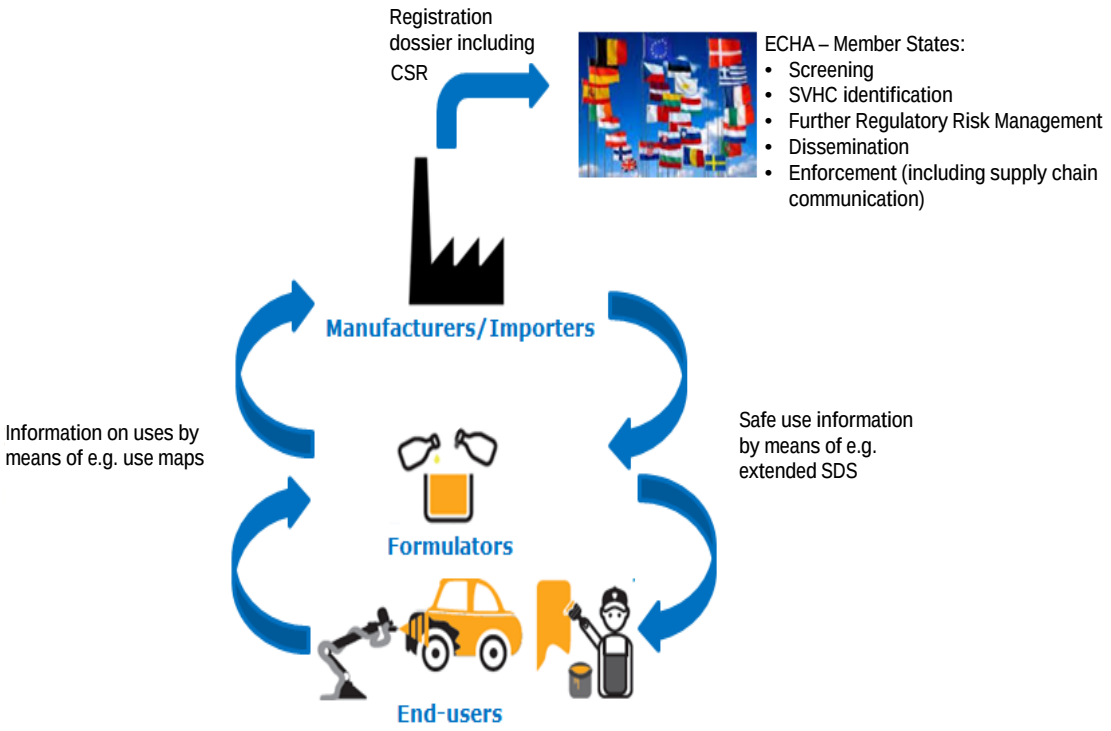
[10] See section 12.4.2.2. for more information on use names.

least ensure a basic understanding by the public at large of where the substance is present, as well as processes and actors that make use of a given substance.

R.12.3.5. Overall information flow

The figure below shows the different processes where use information is conveyed.

Figure R.12- 1: Overview of processes where information on uses play a role



R.12.4. Describing uses

A logical way to describe the uses of chemical substances is to structure them according to the life cycle of the substance. Each life cycle stage can consist of different uses. Each use should be described with a number of elements as explained in section R.12.4.1 and R.12.4.2 below.

[11] See section 12.4.1. for more information on use descriptors.

Section R.12.4.3 shows an example of how all the elements come together in a use description.

R.12.4.1. Key elements for describing a use

A description of a use should include the following elements that are further explained in the sections below:

- Life cycle stage
- Use name and further description of use
- Identification of the markets in which the substance is used
- Description of the different activities contributing to the uses (from human health and environment perspectives)
- Technical function of the substance in the use.

Some additional information is also relevant to describe uses particularly for substances of potential concern (e.g. tonnage information).

In order to facilitate communication in the supply chain, among registrants if applicable, and with authorities, these elements should be structured and their content harmonized as far as possible. The benefits are to enhance consistency among supply chains, and to facilitate IT processing of the information.

The use descriptor system

One means of standardisation is the use descriptor system, which is based on six descriptor-lists with standard entries and codes. It provides categories for some of the key elements of use description. The table below provides an overview on the available categories:

Table R.12- 1: Overview of use descriptor category relevant for each key element describing a use

Use descriptor category	Related key element(s)
Life cycle stage (LCS)	Life cycle stage
Sector of use (SU)	Market description (sector of economy where the use takes place)
Product category (PC)	Market description (type of product), Contributing activities (consumers)
Process category (PROC)	Contributing activities (workers)
Environmental release category (ERC)	Contributing activities (environment)
Article category (AC)	Market description (type of article), Contributing activities (service life)

Use descriptor category	Related key element(s)
Technical function (TF)	Technical function of the substance

The table shows that some categories are relevant for more than one element e.g. product category serves both as an identifier of the market of the substance as well as a contributing activity for consumers. More details are given in the sections below.

The lists of use descriptors for each category are included in Appendix R.12.4.

In order to support full understanding of the scope of a use, use descriptors alone are not sufficient. Tools like IUCLID and use maps therefore include free text fields for the name of the use and each contributing activity as well as for more specific information on the use process. This more specific information can also be standardised via agreements in the supply chains. The use maps can be used as a vehicle to reach such agreements.

R.12.4.2. Brief explanation on each information element describing a use

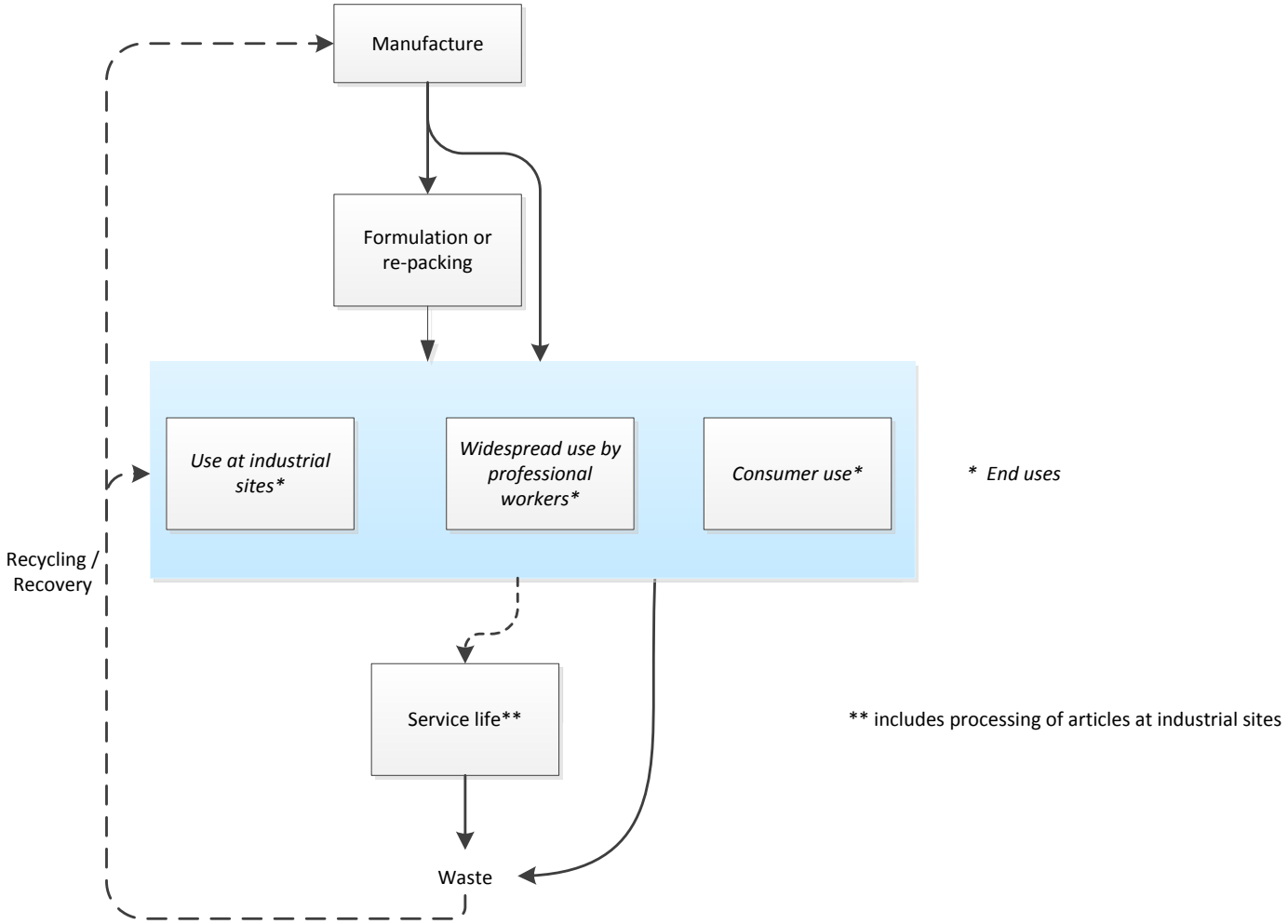
The paragraphs below provide a brief explanation on the different elements that constitute the description of a use. This Guidance does not address whether the elements are mandatory in the context of a registration or not.

R.12.4.2.1 Life cycle stage

The use description should cover the whole life-cycle of the substance, taking into account its degradation/transformation products where applicable. There are four basic steps or stages in the life-cycle of a substance to which a use can be assigned: manufacture, formulation or re-packing, end-use[12] and (article) service life as illustrated below.

[12] 'End-use' means the use of a substance as such or in a mixture, as a last step before the end-of-life of the substance, namely before the substance is consumed in a process by reaction during use (including intermediate use), is emitted to waste streams or the environment or is included into an article.

Figure R.12- 2: Illustration of life cycle concept



Each use of the substance has to be assigned to one of the life-cycle stages. The life-cycle stages are structured in such a way that they provide an indication of the type of organisations concerned by the use (e.g. formulators, industrial sites, small scale professional activities, consumers) and whether the substance is in an article during the use.

The corresponding use descriptor is the **life cycle stage (LCS).**

The life cycle starts with the activities of the first actor in the life of a substance, the manufacturer. In the case of an imported substance, this life cycle stage is not relevant. It continues with the description of the activities of formulators, where relevant. Then activities undertaken by different end-users of the substance as such or in a mixture i.e. industrial companies, professional workers or consumers are to be described. The last stage of the life-cycle of the substance to be considered for use description purposes is the end-use or the service life. The waste stage (disposal or recovery operations) is not to be included in the use description; nevertheless it must be covered in the CSA/CSR.

Manufacture

This stage includes processes by which the registered substance is manufactured from raw

materials. Operations which are necessary for the handling of a substance on its own in the manufacturing for export or placing on the EU market are considered to be part of the manufacturing stage (e.g. filling into appropriate containers, storage, addition of stabiliser, dilution to a safer concentration -if necessary for transport safety-). If a substance is directly exported after manufacture, all activities with the substance refer to manufacturing and should be reported under this stage.

Formulation or re-packing

A use in the formulation stage corresponds to specific activities meant to produce a mixture to be put on the market. This means that during formulation, the substance is transferred and mixed with other substances. It corresponds to activities taking place at industrial sites. Mixing activities during end use are not to be reported under this formulation stage. Manufacturers' or importers' own formulation should be reported under this life cycle stage.

Chemical distributors' activities such as repacking (which involves transfer of the substance) are to be covered under the formulation stage even if no mixing is carried out. It should be noted that if there is repacking (which is a use), the distributor becomes a downstream user for REACH (with all corresponding duties). This also applies to importers transferring substances from large containers into smaller containers without mixing.

Note that distribution, assembling of small containers for transport or re-labelling activities without transfer of substance are not to be considered as "uses" and have therefore not to be reported.

Use at industrial site

All end-uses of the substance (as such or in a mixture) carried out at industrial sites should be reported under this life cycle stage.

A use is an end-use when as its result the substance:

- has reacted (therefore it does not exist anymore in its original form), or
- has become part of an article, or
- has completely been released via waste water or exhaust air, and/or it is contained in waste from this use.

If the substance becomes part of an article, the subsequent life cycle stage (the service life) is to be reported as well (see below).

Please note: manufacturers' or importers' own (end)-uses should be reported under this life cycle stage.

Appendix R.12.3 includes some considerations to help to identify whether a use belongs to this life cycle stage or is rather a widespread use by professional workers.

Widespread use by professional workers

Widespread uses by professional workers correspond to uses carried out in the context of commercial activities and assumed to take place in most towns of a certain size, by multiple actors each at low scale e.g. local garage, small cleaning businesses. They are also considered end-uses. The further fate of the substance corresponds to the fate as described for uses at industrial sites.

Appendix R.12.3 includes some considerations to help to identify whether a use belongs to this life cycle stage or is rather a use in an industrial site.

Consumer use

All end-uses of the substance as such or in a mixture carried out by consumers can be reported under this life cycle stage. Uses by consumers are also considered to take place in a widespread manner.

Service life

For a given substance incorporated into an article, the service life is considered to be the period of time an article remains in service (or in use). The term 'service life of articles' is mentioned in Section 5.2.2 of Annex I to the REACH Regulation.

If a substance ends up in articles, the description of the service life of the substance in articles should be provided. The uses leading to incorporation into the article are to be reported in the previous life cycle stages.

Articles containing the substance can be used or processed by consumers, by workers at industrial sites and/or by professional workers. This also includes processing of semi-finished articles by workers with the aim of producing finished articles or repair and maintenance work like for example sanding of surfaces.

When substances remain in dried coatings, adhesives or comparable mixtures after application in/on the article, one or more uses at service life stage should be reported. If the substance is incorporated in buildings, constructions and parts of them, they should be reported in the same way as when they are incorporated into articles.

Substances for sole use as an intermediate should never have any service life described, as by definition they are transformed during industrial use into another substance, which will then potentially be subject to registration obligations.

During the production of an article a registered substance may react and the transformation product may become part of the article. The parent substance is not regarded as an intermediate (as the transformation product is part of an article), and thus the lifecycle of the substance does not end at transformation. It is therefore expected that the use description of the parent covers the service life stage, even though the parent itself is not present in the article.

In some cases, it might not be easy to determine whether a substance is used as a substance or mixture as such (in which case the use should be documented under the formulation or re-packing, industrial, professional or consumer stages) or whether the substance is an integral part of an article. The ECHA *Guidance on requirements for substance in articles*[13] provides further clarification on the definition of an "article" and decision criteria.

[13] http://echa.europa.eu/support/guidance

R.12.4.2.2 Use name and further description of use

Use name

This element provides the information that characterises the nature and scope of the activities covered in a use and allows understanding of what differentiates this use from the other uses of the substance. Use names should not contain long explanations on technical process, conditions of use or risk management measures.

A unique name/title of the identified use is to be provided. The unique name/title can include sector specific information to support the understanding of the use for different actors in the supply chain. The use name is meant to become the title of the corresponding exposure scenario covering that use. It should also be consistent with the ES short title for communication.

Even though this is a free text field in IUCLID, it is advisable that it is described using standard phrases if available (developed by sectors) as far as possible, in order to ensure consistency between the use name and the title of the exposure scenario to be communicated in the supply chain.

Use names should be limited to key information that helps for example to differentiate one use from another or provide more specificity compared to information provided by the standardised use descriptors.

Use maps are available for a number of sectors including use names agreed at sector level. Therefore they are a good source of harmonised use names for the registration dossier as well as the ES for communication. The use names in use maps provide sector-representative information that is understandable by DU operators. More information is provided in Appendix R.12.1.

Further description of use

Additional information may be provided (as free text in IUCLID) to explain in more detail the use from a technical process perspective. This explanation is mainly aimed at authorities undertaking a detailed analysis of the registration dossier for a better understanding of the uses. This element is not intended to be communicated in the supply chain as part of exposure scenarios, nor disseminated via the ECHA website.

More information on the difference between use name, exposure scenario title, and further description of use is provided in Appendix R.12.1.

R.12.4.2.3 Market description

This element includes information on markets where the substance is used (formulating sectors, industrial sectors, types of products, types of articles).

The corresponding use descriptors are:

- The **sector of use category (SU)** describes in which sector of the economy the substance is used e.g. rubber manufacturing sector, glass manufacturing sector, agriculture, forestry, fishery. 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. If provided, this information may be useful both for downstream users in the assessment of whether the ES is relevant for his use, as well as for authorities to understand/assess the type and number of supply chains concerned by this use.

- The **chemical product category (PC)** describes in which types of chemical products

(= substances as such or in mixtures) the substance is finally contained when it is supplied to, and used by, end-users e.g. detergents, paints. The PC may in particular be specified when a use is specific to one or few products. In the case of uses for which many products are relevant, this element may not be needed as it is not expected to have an exhaustive list of all products. Please note that PC are also used to describe the scope of the consumer exposure assessment. In these cases, the list of PCs is expected to be provided.

- The **article category (AC)** describes the type of article into which the substance has been processed (e.g. wooden articles, plastic articles). This also includes mixtures in their dried or cured form (e.g. dried printing ink in newspapers; dried coatings on various surfaces).

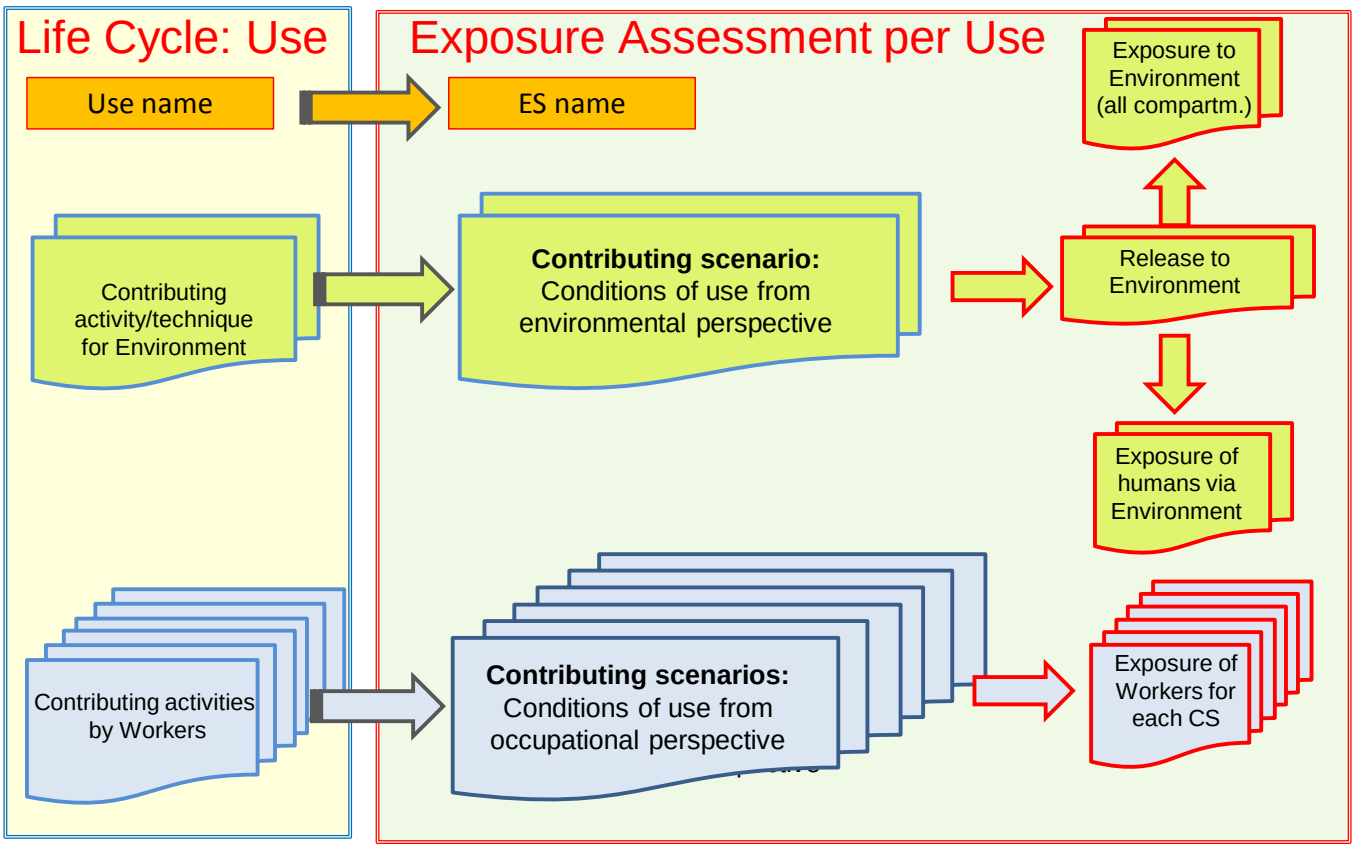
Please note that not all descriptors are applicable to provide this market information at all stages of the life cycle e.g. sector of uses are not relevant for the consumer or formulation or re-packing life cycle stage.

R.12.4.2.4 Contributing activities (CA) description

This element covers the description of the different **activities** contributing to one use. In general, one use corresponds to one exposure scenario. Several activities may take place under one use, leading to several contributing scenarios under one exposure scenario. Activities have a broad meaning here, covering production processes (or process steps), tasks of workers, techniques, unit operations or activities of consumers with particular consumer products/articles. When defining the different contributing activities, material transfer and maintenance should be considered. See also Appendix R.12.1 for more information on use and contributing activities and Appendix R.12.2 on drivers for splitting into uses or activities.

For each use, at least one contributing activity needs to be reported in IUCLID for human health and environment. When an exposure assessment of the use is performed, each of the contributing activities is assessed to demonstrate that its conditions of use are safe. Uses and contributing activities will translate into exposure scenarios and contributing scenarios in the chemical safety assessment. The figure below illustrates these concepts in the case of a use by workers.

Figure R.12- 3: Illustration of the concepts of use / contributing activity and exposure scenario / contributing scenario



1

The following elements should be provided for each contributing activity:

A contributing activity name

The contributing activity name allows for more specificity than the corresponding use descriptors (see below). As for the use name, this is a free text field in IUCLID where the nature and scope of the activity/technique are to be briefly defined. It is advisable that it is described using standard phrases developed by sectors as far as possible in order to ensure consistency between the contributing activity name and the title of the contributing scenario to be communicated in the supply chain.

The corresponding use descriptor

Each contributing activity should be linked to a standardised use descriptor category:

- The **process category (PROC)** describes the tasks, application techniques or process types defined from the occupational perspective, including use and processing of articles by workers.

- The **environmental release category (ERC)** describes the activity from the

environmental (release) perspective. One ERC is assigned to one contributing activity (environmental perspective) but it can be linked to one or more contributing activities from an occupational perspective (e.g. several PROCs per ERC). This means that one set of environmental conditions for a use can be connected to several sets of operational conditions (OC)/ risk management measures (RMM) for the different activities of workers carried out at this site.

- The **Product category (PC)** describes the contributing consumer activities and **Article Category (AC)** also the contributing service life activities for consumers[14].

Many of the use descriptors (PCs, PROCs, ERCs, ACs) can be used as input parameters to derive exposure estimates in modelling tools such as ECETOC-TRA. In this case, consistency with the domain of applicability of the descriptor in the context of the tool should be ensured.

For more information on contributing activities, please go to the section 'Identifying activities contributing to a use' in Appendix R.12.2.

R.12.4.2.5 Technical function of the substance

This element indicates the technical function of the substance meaning what the substance actually does in the use (e.g. solvent, pigment). The corresponding use descriptor is the **technical function**.

The technical function should be clearly distinguished from the Product Category (PC). For example, a substance can be used in anti-freeze products (PC4) without being itself an anti-freezing agent. It could be a colouring agent in the anti-freeze product. This information should be conveyed in the registration dossier and the safety data sheets).

R.12.4.3. Additional information on use

The IUCLID structure provides the registrants with the opportunity to complement the use description with additional information on use that are of particular relevance for substances of potential concern (in terms of hazard profiles or data gaps) for which regulatory actions may be needed. Where such information is available in the registration dossier authorities will take it into account when determining the relative priority of substances for further scrutiny (e.g. screening), and when refining their analysis on the regulatory effectiveness of any further action.

- **Tonnage information**

In IUCLID the registrant has the opportunity to indicate the tonnage going to each (type of) use of the substance.

Where such information is available authorities are able to differentiate between the part of the total tonnage marketed which is relevant for further regulatory actions and the part of the marketed tonnage which is of lower/no relevance (e.g. tonnage for uses outside the scope of authorisation/restriction or tonnage for uses for which rigorous containment are already applied). Authorities are interested in working first on substances for which regulatory actions will have the biggest impact. Where no information on the share of the tonnage per (type of)

[14] As explained above, PCs can also serve as market information for workers' uses and ACs for service life uses for workers.

use is available worst case assumptions have to be made.

It is not expected that exact figures on the marketed tonnage are provided and kept up-to-date. In most cases rough estimation will be sufficient to describe the extent of a use. It is however essential for registrants to document the assumptions and rationale behind the tonnage reported (e.g. sources of information for the estimates).

Please note: Tonnage information is also needed for environmental assessment based on EUSES. The tonnage per use serves as input for the regional assessment as well as a basis for estimations of site or generic tonnages in the local assessment. Further explanations are provided in the Guidance on Chemical Safety Assessment, chapter R16.

- **Use specific regulatory status**

With this field the registrant can indicate that one or some of his uses are exempted from REACH requirements such as applying for authorisation. For authorities it is particularly relevant to be able to identify such uses without ambiguities at an early stage of the regulatory process i.e. when selecting and prioritising substances for further regulatory actions, potentially using IT-algorithms. This is to avoid targeting substances for which regulatory actions under REACH would be ineffective or of low effectiveness compared to other substances.

Information on the use specific regulatory status is particularly relevant where it can be combined with information on the tonnage allocated to that use.

Some examples that can be flagged:

- Use as on site isolated intermediate (REACH Article 2 (8) or Article 49)
- Use in biocidal products (REACH Article 56(4)(b))
- Use in cosmetics products (REACH Articles 56(5)(a) or 67(2) or 14(5)(b))

Explanations can be provided for the claim of the specific regulatory status of the use, e.g. by providing the reference to the relevant legislation and the details related to the specific regulatory status and demonstrating that the criteria for a certain exemption are fulfilled.

- **Limited number of sites for this use**

With this field the registrant can claim that the use described takes place only in a limited number of industrial sites across EU. The information may serve as indirect proof of absence of widespread uses[15], together with other criteria. Such information may be relevant for authorities when prioritising substances for further scrutiny or regulatory action (a substance only used at a low number of sites would justify lower priority for further regulatory actions compared to substances used at high number of sites, other criteria being equal).

[15] The field is only available for uses described under the life-cycle stages ‘formulation’ and ‘uses at industrial sites’. It is not relevant for the life-cycle stage ‘widespread use by professional workers’, ‘consumer use’ and ‘service life’ as these are considered widespread by definition. See Appendix R.12.1 for more information on widespread.

It should be noted that IUCLID includes still some other fields related to use description such as:

- 'Substance as such/in a mixture' (indication whether the substance that is subject to registration is supplied to the use as a substance, or whether it has been incorporated into a mixture),
- 'Subsequent service life relevant to this use' (indication whether the use leads to the inclusion of the substance into an article and/or the substance remains in a dried or cured mixture on the surface of an article),
- 'Substance intended to be released from article' (when describing service life: indication whether the substance is intended to be released).

The IUCLID manual includes information on these fields.

R.12.4.4. Examples

Examples illustrating how all these elements contribute to the description of one use are given below:

Table R.12- 2: Example of description of use[16]

Life cycle stage	Use name	Further description of use	Market description	Contributing activity (CA) name	CA descriptor	Other information
Use at industrial site	Use of vehicle cleaning product	Spraying and rinsing of cleaning product at car manufacturing lines (largely automated process – mainly open – ambient temperature)	PC35, SU17	Automated water based washing of large articles – Indoor use	ERC4	Technical function of substance in this use: surfactant Tonnage per use: 100 t/y (Total EU tonnage for this use) Use specific regulatory status: no Limited number of sites for this use: no Subsequent service life relevant to this use: no Supplied as a mixture
				Transfer of products with manual coupling/decoupling	PROC8b	
				Spraying and rinsing of a diluted cleaning product (automated process; open systems)	PROC7	

[16] This example is for illustration purposes only. It does not mean that all the elements included in the example to describe a use are mandatory in the context of registration.

Table R.12- 3: Example of description of use using standard phrases[17]

Life cycle stage	Use name	Further description of use	Market description	Contributing activity name	Contributing activity descriptor	Other information
Widespread use by professional workers	Professional use of general surface cleaning products	Regular cleaning of equipment. Manual spraying and wiping using long-handle tool	PC35	Application of solvent borne or water-borne products; Indoor use	ERC8a	Technical function of substance in this use: solvent; Tonnage per use: 100 t/y (Total EU tonnage for this use) Specific regulatory status: no Limited number of sites for this use: no Subsequent service life relevant to this use: no Supplied as a mixture
				Manual spraying	PROC11	
				Wiping	PROC10	

[17] Standard phrases from ESCom catalogue of standard phrases available at: http://www.cefic.org/Industry-support/Implementing-reach/escom/

Appendix R.12.1. Clarification of terms and concepts

Uses, identified uses and exposure scenarios

The REACH definition of **use** is given in Article 3, point 24: *use: any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation*.

It should be noted that according to this definition the manufacture of a substance, the distribution of chemicals (where no repacking occurs) or buying and selling are not regarded as uses under REACH, however, activities like manufacturing and storage should be considered in the chemical safety assessment. Transport as such is out of the scope of the REACH Regulation (Article 2(1)(d)).

The REACH definition of **identified use** is given in Article 3, point 26: *identified use: means a use of a substance on its own or in a mixture, or a use of a mixture that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user*.

When CSA obligations apply, the registrant is expected to cover all the identified uses in his registration dossier and generate the related exposure scenarios. Uses for which safe use has not been demonstrated by the registrant in exposure scenarios should be identified as 'uses advised against' or be addressed by the Downstream user by a DU Chemical Safety report including the corresponding notification to ECHA.

Unforeseeable uses are not intended and are therefore also excluded from the scope of the "identified uses".

There are some uses of substances which are not considered "identified uses" either: the use of (the substance in) articles. This is due to the fact that the definition of identified use refers to the substance on its own or in a mixture.

According to REACH Annex I, registrants who are required to carry out a Chemical Safety Assessment (CSA) with exposure assessment have to address all stages of the life-cycle of the substance including those resulting from the manufacture and identified uses if they happen in the EU (e.g. the use of substances in articles). Therefore, **exposure scenarios** (ES) should address the manufacture and such uses (although ES for manufacturing may not be relevant for communication in the supply chain). The description of the identified uses should be consistent with the titles and the content of the exposure scenarios. This consistency is a legal requirement laid down in section 5.1.1 of Annex I of REACH.

In general, a 1:1 relationship between use and ES is expected. However, there are cases in which uses will not have a corresponding ES (e.g. uses covered by exemptions such as the use of a substance as a food additive in foodstuffs). There can also be cases where exposure assessments have been carried out, but they cannot easily be linked to a particular use e.g. assessment of waste stage. In some other cases due to the exposure assessment strategy, one ES can cover several uses or several CA, e.g. measured/monitoring data covering several tasks, manufacturing and formulation taking place at the same site. However, in this case, for the purpose of use description, the uses and CAs should be described separately.

It is also important to trace which use is covered in which exposure scenario, in order to (i) check whether the exposure assessment is complete and (ii) track back the operational conditions (OC) and risk management measures (RMM) applying to a given use to verify their plausibility. This might be part of dossier/substance evaluation and

impact the selection and prioritisation of substances of concern.

The use maps developed by downstream user associations are a good source of links between uses and input to the chemical safety assessments.

Use name, ES title, structured short title and further description of use

The terms above have sometimes been a source of confusion. The table below provides an overview of their main differences and purposes including examples:

Table R.12- 4: Use name, ES title, structured short title and further description of use

	Purpose	Explanation	Standardisation	Present in registration dossier (if yes, IUCLID section/ field)	Present in supply chain communication (If yes, where in the ES[18])	Example
Use name	To provide a good indication of the scope of the use. In cases where exposure assessment is done, the use name eventually becomes the ES title. The audience is therefore registrants (when use names are developed by downstream users via use maps), authorities (to understand the scope of the use) and downstream users (when receiving the use name as ES title in the exposure scenarios)	This name is important to uniquely label the nature and scope of the activities covered by the use. The use name should be short. Further details on the use can be provided in the further description of the use and in contributing activity names.	At sector level via use maps	YES: -IUCLID field 'Use name' or 'Manufacture name' or 'Service life name' - CSR: field 'ES name'	YES, section 1 Title section/ field 'ES/use name'	Use of vehicle cleaning products
ES short title	To allow the DUs	ES short title for the	Built from use	NO	YES, field 'ES title	Use at industrial site;

[18] Sections/ fields referred to in the table come from the ES annotated templates published by ECHA: http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

	Purpose	Explanation	Standardisation	Present in registration dossier (if yes, IUCLID section / field)	Present in supply chain communication (If yes, where in the ES[18])	Example
for communication	receiving the extended SDS to sort out the relevant ES from the Annex to the SDS	table of content at the beginning of the annex with the ES in the safety data sheet.	descriptors following guidelines presented at ENES[19].		[short title]'	Washing and cleaning products
Further description of use	To have a better understanding of the use and the processes covered. The audience is therefore registrants (when the further description of use is developed by downstream users via use maps), and authorities (to understand the details on what the use covers).	It describes the technological process(es) carried out under this use. Where appropriate, it refers to the contributing activities/techniques. The information provided here should be both concise and sufficiently concrete to support the understanding of readers who are not familiar with the details of the technologies in the sector.	NO	YES, IUCLID field 'Further description of use'	NO	Spraying and rinsing of cleaning product at car manufacturing lines (largely automated process – mainly open – ambient temperature)

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[19] http://www.ducc.eu/News.aspx#news5

Uses advised against

Annex VI of REACH (information requirements referred to in Article 10) states that, where applicable, an indication of the uses which the registrants advises against and why (i.e. non-statutory recommendations by supplier) shall be provided.

In addition, Article 37(3) of REACH further specifies that where the manufacturer or importer, having assessed a use in accordance with Article 14, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream users with the reason(s) for that decision and shall include this use as a use advised against in his registration.

A use advised against is therefore understood as a use that the registrant is aware of (either because it has been communicated by the downstream user or because of his own knowledge). He may have considered it unsafe after carrying out the CSA, or he may have decided not to carry out an assessment and to advise against the use for reasons of precaution. In both cases the responsibility to conduct a CSA falls on the DU. Hence, the use advised against can still be carried out in the EU, provided that a DU has assessed it to be safe in a DU CSA and has done the corresponding notification to ECHA according to Article 38.

Reasons why registrants may decide to advise against a use include that this use has undergone a CSA in accordance with Article14 and no RMMs were sufficient to adequately reduce possible risks for humans or the environment, but the legal text is not limitative. Other reasons why registrants may wish to advise against uses include:

- policy decision of the registrant e.g. to dissuade any wide dispersive use of the substance or to push towards other alternatives for that use;
- conservative human health or environment protective reasons or preventive advice e.g. advising against some uses without having performed a CSA;
- technical reasons limiting the use in certain conditions;
- assessment of the use considered as not feasible or not economical.

Where a use is advised against, providing the reason why is also a requirement. It is suggested that the registrant systematically documents at least whether it results from the conclusions of a CSA duly performed in accordance with Article 14 or from other considerations.

Note that the section on “Uses advised against” in the registration dossier does not aim at describing limitation to the uses of the substance that originates from specific Community or National provisions in relation to protection of human health or the environment (such as uses restricted under Title VIII of REACH). As an example there is no need to indicate ‘consumer uses’ as uses advised against in the registration dossier of a CMR substance. Such information does not have to be communicated as part of the registration dossier but must be communicated in the supply chain as part of any SDS related to the substance as such or in a mixture (in subsection 1.2 of the SDS).

The uses advised against by a supplier are to be indicated in subsection 1.2 of the SDS e.g. ‘Do not use for private purposes (household)’. The information on the uses advised against in the registration dossier shall be consistent with the information in subsection 1.2 of the SDS.

In practice, uses advised against may be described using the same elements as the identified uses.

Widespread and Wide-dispersive use

The terms ‘widespread’ and ‘wide-dispersive’ are commonly used to qualify uses. The

two terms reflect different characteristics and are often wrongly interchanged.

'Wide-dispersive' and 'widespread' are concepts used in the context of selection and prioritisation of substances for further regulatory processes e.g. wide dispersive use is mentioned in Article 58 as a criterion to support the prioritisation of substances to be recommended for inclusion in Annex XIV.

The 'widespread' concept also applies to the prioritisation of substances for testing proposals where for instance the legal text (Article 40 (1)) mentions that priority shall be given to substances with 'uses resulting in widespread and diffuse exposure'.

'Widespread' means that the substance is used at many sites and/or by many users.

'Wide-dispersive' means:

- For the environment: widespread and potential for release
- For human health: widespread and potential for exposure

In summary:

Wide-dispersive = widespread + potential for release/ exposure

The Table R.12- 5 below illustrates all the possible combinations and the resulting conclusion on whether or not a use is considered wide dispersive.

Table R.12- 5: Illustration of the different scenarios leading to the conclusion on the character wide-dispersive of uses

	Use 1	Use 2	Use 3	Use 4
Use at many sites, by many users (i.e. widespread)	Y	Y	N	N
Potential for release / exposure	Y	N	Y	N
Conclusion: Wide dispersive?	**Y**	**N**	**N**	**N**

Some default assumptions are made on the characteristic "widespread" of the substance depending on the life cycle stage whereas in other cases it is up to the registrant to justify:

- Uses reported under the life cycle stage 'consumer use', 'widespread use by professional workers' and 'service life' (consumer) are considered by definition widespread.
- Uses reported under the life cycle stage 'Formulation' and 'use at industrial sites' are not upfront considered widespread as the uses under those life cycle stages can take place at only a few number of sites and/or involve few users. The information on the limited number of sites/users is taken into consideration where available.

Information on the absence of release/exposure (rigorous containment) is also considered where available.

Appendix R.12.2. Drivers for splitting into uses and into contributing activities

Split into uses

Differentiation between uses and subsequently exposure scenarios may be driven by:

- Targeted Communication in the chain: the need to establish efficient and useful communication between suppliers and users on the safe conditions of use may drive the naming and the scope of exposure scenarios;
- Needs to enable a consistent and transparent exposure assessment and risk characterisation for each use. This may lead to differentiation into different uses if the conditions under which the contributing activities are carried out significantly vary;
- Different regulatory implications or legal requirements e.g. uses with specific exemptions.

Uses should be described according to the life-cycle stages. Within one life-cycle stage the clustering or splitting into different uses (or ES) largely depends on the recipient of the ES. For example, a registrant would possibly not combine lubricant products and cleaning products within one exposure scenario, as the recipients (formulating sectors) may be different.

A registrant may structure his market according to his customers in the different formulating sectors (by type of product these sectors produce) and/or end-use sectors (by sector of economy finally using the substance as such or in a mixture). If he only sells the substance directly to end-users, the formulation or re-packing stage is left out.

The differentiation among uses and contributing activities, including their names should ideally be defined at sector level (names to become standard phrases in the future) and can provide more specificity than the standardised use descriptors, as explained in section R.12.4.2.2.

Each sector will decide for itself how to carry out differentiation into uses and contributing activities, based on available information on input for the exposure assessment as well as existing processes/products in the sector. The variation in the type and extent of hazard of substances entering into a use need to be taken into account.

There may be uses that are similar although carried out in different markets. In these cases registrants may decide to cover several types of chemical products (PC) or sectors of end-use (SU) or article (AC) in one use. For example the process to produce formulations can be exactly the same regardless of whether a detergent or a paint is produced.

Identify activities contributing to a use

Different activities, processes (or process steps), tasks or unit operations can contribute to a use reported in the registration dossier.

The split into activities is largely driven by the assessment of substances for which exposure scenarios are to be generated. One contributing activity/technique will in general correspond to one set of exposure estimates and one set of RMMs/OCs i.e. one

contributing scenario.

From the environmental release perspective the focus is on the type of technique(s) operated at a site: e.g. techniques leading to different emission factors and potentially requiring different types of environmental RMM will be covered in different "contributing activities". The contributing scenario relates to the conditions at a site (or an installation[20] at a site) all together leading to waste water, waste air or waste. It does not refer to single tasks or processes as defined for worker assessment. If the same use (type of site or type of installation at a site) could be carried out under various conditions in different sites (e.g. large site with extensive risk management and small sites with less effective control measures) two or more contributing techniques should be defined. It is important to clearly reflect in the name of the contributing activities/scenarios the scope and differences of their coverage.

From the human health perspective the focus is on the worker's task or process performed, or product/article used by the individuals.

For **workers'** uses, it translates into a set of tasks/processes happening at the same site (or within the same professional undertaking). When exposure assessment has been carried out, each contributing scenario corresponds to a specific activity/task/process performed by workers.

Registrants need to consider whether some specific activities such as transfer, maintenance, sampling, etc. need a separate contributing activity. If they are included in a more general contributing activity it is recommended to make this clear in the contributing activity name e.g. '…including maintenance'.

In the exposure scenario, the conditions driving exposure to humans and to the environment are to be consistent. Operational conditions (OC) and risk management measures (RMM) regarding occupational exposure are usually task - or workplace - related. Releases to the environment are however mostly assessed at industrial site level or at the level of a standard municipality. Consequently one set of environmental OC and RMM related to a representative site for a use can be connected to several sets of OC/RMM for the different activities of workers carried out at this site. Even if the same activity of workers is carried out under different conditions at this site, these conditions can be still consistent with the one set of conditions related to the environment.

For **consumers** each contributing activity within one use corresponds to either a general product type (e.g. washing and cleaning products) or to a specific product type (e.g. floor cleaning product, dish washing product). These contributing activities can be grouped under the same use as long as they have the same release pattern to the environment (e.g. grouping all down-the-drain products in the same use with the different product types in different contributing activities).

[20] "Installation" is a term that plays a key role in environmental permitting system for large sites. Industrial Emissions Directive (IED) permits are often given for installations rather than sites. An installation has usually an own building (with its own waste water and waste air streams).

Appendix R.12.3. Differentiation between uses at industrial sites and widespread uses by professional workers

The REACH legal text differentiates between industrial and professional use [activity] in definitions 13, 25 and 35, as well as section 6 of Annex VI. In Annex XVII also the terms "industrial installation" and activity of a "professional outside industrial installations" are used. However, no detail is given on the difference between the two and clarification is needed to support companies in this decision.

The terminology "industrial" and "professional" is used in two different contexts:

- To differentiate between life cycle stages
- To define the level of occupational health and safety management systems applied in companies[21].

It is recommended to understand the concept "professional" as a characteristic to distinguish between use: i) at industrial sites and ii) uses outside industrial sites (but not consumers or general public). This will lead to different life cycle stages in terms of use description.

The following table provides a non-exhaustive list of characteristics associated with industrial sites and professional activities outside industrial sites, and can be used in a weight of evidence approach to determine whether a use is considered: as 'use at industrial site' or as a 'widespread use by professional workers'.

Table R.12- 6: Characteristics helping in differentiating between industrial sites and professional activities outside industrial sites and relation with the life cycle stages

Life cycle stage	Use at industrial site	Widespread use by professional workers
REACH Legal text	Industrial use (activity)	Professional use (activity)
Number of places where substance is used (at EU level)	Low to high	High
Number of persons potentially in contact (at EU level)	Low to high	High

[21] This is called industrial/professional "settings" in ECETOC TRA.

Type of enterprises, type of business, examples	• Production sites • Large construction sites • Large maintenance/repair and service sites	Services (mobile or stationary micro sites), administration, education, small building and construction works
Number of users/enterprises proportional to size of municipality by inhabitants	No	Yes
Activity requiring a permit according to the Industrial Emissions Directive (IED)	Often yes	Usually not
Availability of capital intensive equipment for automation and engineering controls	Often yes	Usually not, but can be
Amount of processed chemicals per single enterprise/actor	Low to high	Low
Connection to public sewer	Often yes, sometimes not	Yes
Tonnage reference for local environmental standard assessment	Tonnage for one representative industrial site per use (industrial point source)	Tonnage per use proportional to 10,000 inhabitants (municipal point source)

Examples

The following list includes typical examples for business involving chemicals which would be considered as “widespread use by professional workers”:

- Building and construction business with broad variety of activities (mostly micro companies)
- Maintenance services for office/household equipment
- Indoor cleaning services for all kind of buildings
- Facade cleaning services
- Car wash and other car care services
- Hairdressing and other beauty services

- Health care services

Typical examples for business involving chemicals which would be considered as “uses at industrial site” are:

- Production of cars and other vehicles
- Production of paper
- Textile dyeing and finishing
- Production of semiconductors

There are also cases which are considered ‘borderline’ i.e. it is more difficult to conclude on their Life cycle stage. Some examples have been listed below including some possible approaches:

a) Industrial cleaning services carried out by small or large, well-trained or less trained service providers. This can include tank-cleaning, boiler cleaning, cleaning of machinery, etc. at industrial sites. This case should be regarded as a ‘use at industrial site’ regardless if the actual work is carried out by employees of the site or by external service providers. The resulting releases will be from the site where the cleaning operation takes place;
b) Workshops for car repair and finishing. The sites may be small but could be also large. The predominant characteristic of the business is the huge number of small enterprises and the correlation to the municipal infrastructure (population density) so they should be reported as ‘widespread use by professional workers’. In some cases, the workers’ protection standards under which these businesses operate are similar to those of the car industry. This can be reflected when performing the human health exposure assessment by e.g. selecting the conditions of uses corresponding to ‘industrial’ settings;
c) Consumer textile cleaning with solvents and other heavy duty or specialised chemicals in micro-workshops. The predominant characteristic of the business are the small size of the enterprises and the correlation to the municipal infrastructure so they should be considered as ‘widespread use by professional workers’, even though a high level of engineering control may be applied;
d) Large sites for water based washing/cleaning of textiles used in industry (cleaning wipes and work wear). These should be considered as ‘uses at industrial sites’. The number does not correspond to the size of the municipality as few large sites normally serve a bigger region. Extensive and site-specific treatment infrastructure for wastewater and waste are normally present;
e) Large sites for maintenance and repair related to public transport infrastructure (trains, airports/harbours). These cases should be considered as ‘uses at industrial sites’. The structure of the service for trains, ships and planes does not correlate with the municipal infrastructure. Sites for maintenance of buses and trams are more closely related to the municipal infrastructure. Nevertheless usually their size is sufficiently big to treat them as an industrial site.

With regards to the use of the terms “industrial” and “professional” in the context of human health exposure assessment, they flag the occupational conditions under which the workers use a substance or product. In general, it is assumed that ‘industrial’ conditions are associated with training of workers, proper work instructions and supervision. The use of exposure assessment models can result in different exposure estimates depending on the type of conditions selected (industrial or professional) e.g.

industrial conditions may assume a higher level of effectiveness for RMM.

Actually, a use can take place 'at industrial site', but for workers exposure assessment a lower effectiveness of RMM may be assumed ("professional setting"), as for example when workers from a contractor cleaning machinery between shifts in an industrial site. There may also be uses where the opposite is the case, well trained, instructed and equipped mobile services with chemicals (e.g. biocides).

The table below illustrates the two aspects and how they relate to each other in different examples.

Table R.12- 7: Illustration of LCS vs occupational health and safety management systems

Life cycle stage	Occupational health and safety management system	Example
Use at industrial site	Advanced ('industrial conditions' or similar)	Use of substance as intermediate in manufacturing process
	Basic ('professional conditions')	Contractors working in an industrial site on cleaning tasks
Widespread use by professional workers	Advanced ('industrial conditions' or similar)	Application of biocidal products by specialised companies
	Basic ('professional conditions')	Self-employed painter painting in private households

Appendix R.12.4. List of use descriptors

Descriptor list for Life cycle stages (LCS)

The Life cycle stage description gives information on the step of the substance life where the use takes place. The life cycle starts with the first LCS Manufacture, then it generally continues with the introduction of the substance into a mixture by formulators to conclude with different end-uses such as the use at industrial sites, or the use by professional workers or consumers. An end-use can result in the inclusion of the substance into articles, in which case the service life stage is relevant.

The Life cycle stage descriptor is meant to indicate:

- The type of organisations concerned by the use (which implicitly can provide

some information on the potential for release/exposure of the substance);

- Whether the use refers to a substance in an article.

Clarification on the scope of each of the life-cycle stages is provided in Section 0.

Table R.12- 8: Descriptor list for Life cycle stages

Code	Name
M	Manufacture
F	Formulation or re-packing
IS	Use at industrial sites
PW	Widespread use by professional workers
C	Consumer use
SL	Service life

Descriptor list for Sectors of use (SU)

The categories for Sector of use are meant to provide information on the sector of the economy or market area where the use takes place. They therefore indicate types of industries or industry segments where the substance is present.

If the manufacturer/importer or the downstream user is unable to identify a suitable sector of use category from the list, the category "SU0 - other" can be selected and the type of sector should be specified. If possible, a code (and the corresponding phrasing) from the NACE system[22] should be selected to describe such a sector.

Table R.12- 9: Descriptor list for Sectors of use (SU)

Code	Name	NACE codes
SU1	Agriculture, forestry, fishery	A
SU2a	Mining, (without offshore industries)	B
SU2b	Offshore industries	B 6
SU4	Manufacture of food products	C 10,11
SU5	Manufacture of textiles, leather, fur	C 13-15
SU6a	Manufacture of wood and wood products	C 16
SU6b	Manufacture of pulp, paper and paper products	C 17
SU7	Printing and reproduction of recorded media	C 18
SU8	Manufacture of bulk, large scale chemicals (including petroleum products)	C 19.2+20.1
SU9	Manufacture of fine chemicals	C 20.2-20.6
SU11	Manufacture of rubber products	C 22.1
SU12	Manufacture of plastics products, including compounding and conversion	C 22.2
SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement	C 23
SU14	Manufacture of basic metals, including alloys	C 24
SU15	Manufacture of fabricated metal products, except machinery and equipment	C 25

[22] European Commission, Competition: List of NACE Codes (2007.11.19); http://ec.europa.eu/comm/competition/mergers/cases/index/nace_all.html

SU16	Manufacture of computer, electronic and optical products, electrical equipment	C 26-27
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	C 28-30,33
SU18	Manufacture of furniture	C 31
SU19	Building and construction work	F
SU20	Health services	Q 86
SU23	Electricity, steam, gas water supply and sewage treatment	D 35, D36-37
SU24	Scientific research and development	M72
SU0	Other	

Descriptor list for Chemical Products Category (PC)

The Chemical Product Categories as defined in this guidance have two functions:

i) they describe the sectors formulating mixtures by mixture types (information relevant at formulation life-cycle stage). The categories listed help to further structure the uses of the substance along the supply chain based on the product types;

ii) they describe the product types used by the end-users (industrial, professional or consumer end-users). The product type implicitly includes some information on the potential for exposure/release of the substance.

The product category does not aim at characterising the specific technical function of the substance but rather the type of mixture in which the substance is contained.

The product categories are not further divided into sub categories; the number of the Product Categories already ensures an efficient description of formulating mixture and products types used by end users. However, exposure estimation tools might require further differentiating the products for consumer exposure assessment. The subcategories of product defined in the ECETOC TRA exposure assessment tool are listed and described in Chapter R.15 of the IR&CSA Guidance. If the manufacturer/importer or the downstream user is unable to identify a suitable product category from the list, the category "PC0 - other" can be selected and the type of product should be specified. If possible, a code (and the corresponding phrasing) from the Nordic system of Categories (UCN)[23] should be selected to describe such a product.

Table R.12- 10: Descriptor list for Chemical Products Categories (PC)

Code	Name	Explanation and examples
PC1	Adhesives, sealants	
PC2	Adsorbents	
PC3	Air care products	
PC4	Anti-Freeze and de-icing products	
PC7	Base metals and alloys	

[23] http://195.215.202.233/DotNetNuke/Portals/0/DNNPortal-Download/Funktionskoder-eng%20htm.htm

PC8	Biocidal products	Includes e.g. disinfectant products, pest control products. Note that the category refers to types of products, not to the technical function of the substance. PC 35 should be assigned to disinfectants being used as a component in a cleaning product.
PC9a	Coatings and paints, thinners, paint removers	
PC9b	Fillers, putties, plasters, modelling clay	
PC9c	Finger paints	
PC11	Explosives	
PC12	Fertilizers	
PC13	Fuels	
PC14	Metal surface treatment products	This covers substances permanently binding with the metal surface. It includes e.g. galvanic and electroplating products.
PC15	Non-metal-surface treatment products	It includes e.g. example treatment of walls before painting.
PC16	Heat transfer fluids	
PC17	Hydraulic fluids	
PC18	Ink and toners	

PC19	Removed from PC list and relocated in the technical function list (Table R.12- 15)[24].	
PC20	Processing aids such as pH-regulators, flocculants, precipitants, neutralization agents	This category covers processing aids used in the chemical industry.
PC21	Laboratory chemicals	
PC23	Leather treatment products	This category includes dyes, finishing, impregnation and care products.
PC24	Lubricants, greases, release products	
PC25	Metal working fluids	
PC26	Paper and board treatment products	This category includes e.g. bleaches, dye, finishing, impregnation products and other processing aids.
PC27	Plant protection products	
PC28	Perfumes, fragrances	
PC29	Pharmaceuticals	
PC30	Photo-chemicals	
PC31	Polishes and wax blends	
PC32	Polymer preparations and compounds	
PC33	Semiconductors	

[24] For further advice on how to adapt to this change please see Appendix R.12.5.

PC34	Textile dyes, and impregnating products	This category includes e.g. bleaches and other processing aids.
PC35	Washing and cleaning products	This category includes water and solvent based products.
PC36	Water softeners	
PC37	Water treatment chemicals	
PC38	Welding and soldering products, flux products	
PC39	Cosmetics, personal care products	This category includes products covered by the Cosmetics Regulation (EU Regulation 1223/2009) and other personal care products. It includes products such as. toothpaste, deodorants, etc.
PC40	Extraction agents	
PC41	Oil and gas exploration or production products	
PC42	Electrolytes for batteries	Mixtures (liquids or pastes) designed to serve as electrolytes in batteries.
PC0	Other	

Descriptor list for Process Categories (PROC)

The process categories define tasks, or process types from the occupational perspective. The PROCs are also differentiated by taking into account the exposure potential for workers during the respective tasks or process types. This descriptor can be assigned to workers' activities contributing to a use. The categories are meant to support harmonised and consistent exposure assessment across sectors and supply chains.

The use descriptor included in the description of use is expected to reflect the nature and scope of the activities. The explanations and examples below should be looked at in order to ensure that the process category assigned is appropriate.

When no appropriate descriptor is available "PROC0 - other" should be selected and a description should be provided.

Table R.12- 11: Descriptor list for Process categories (PROC)

Code	Name	Explanations and examples
PROC1	Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.	Describes the general nature of processes taking place in sectors where the manufacture of substances or production of mixtures takes place or processes with closed process conditions as applied in chemical industry[25]. The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge the system are not included.
PROC2	Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions	Describes the general nature of processes taking place in sectors where the manufacture of substances or production of mixtures takes place (continuous processes that involve limited manual interventions), or processes with equivalent closed process conditions as applied in chemical industry. The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge the system are not included.

[25] The equivalent conditions need to be described in the exposure scenario and the related exposure estimate should be associated with an explanation in the CSR. For further information, please see Chapter R.14 of the IR&CSA Guidance.

PROC3	Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition	Describes the general nature of processes taking place in sectors where the manufacture of substances or production of mixtures takes place (batch processes that involve limited manual interventions) or processes with closed process conditions as applied in chemical industry. The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge are not included.
PROC4	Chemical production where opportunity for exposure arises	Describes the general nature of processes taking place in sectors where the manufacture of substances or production of mixtures takes place (processes where the nature of the design does not exclude exposure). The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge the system are not included.
PROC5	Mixing or blending in batch processes	Covers mixing or blending of solid or liquid materials in the context of manufacturing or formulating sectors, as well as upon end use. Charging/discharging of the blending vessel and sampling are considered separate activities and are not included in this PROC.
PROC6	Calendering operations	Processing of large surfaces at elevated temperature e.g. calendering of textile, rubber or paper
PROC7	Industrial spraying	Air dispersive techniques i.e. dispersion into air (= atomization) by e.g. pressurized air, hydraulic pressure or centrifugation, applicable for liquids and powders. Spraying for surface coating, adhesives, polishes/cleaners, air care products, blasting. The reference to 'industrial' means that workers involved have received specific task training, follow operating procedures and act under supervision. Where engineering controls are in place, they are also operated by trained personnel and regularly maintained according to procedures. It is not meant that the activity can only take place at industrial sites.

PROC8a	Transfer of substance or mixture (charging and discharging) at non-dedicated facilities [26]	Covers general transferring operations of large quantities of chemicals from/to vessels, containers, installations or machinery without dedicated engineering controls in place for reducing exposure. Transfer includes loading, filling, dumping, bagging and weighing.
PROC8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities[26]	Covers general transferring operations from/to vessels or containers with provision of dedicated engineering controls in place for reducing exposure: it addresses operations where material transfers are undertaken at locations that are specifically designed and operated for the transfer of larger quantities (tens of kilos and higher) of chemicals and where the exposure is primarily related to the un-coupling/coupling activity rather than the transfer itself. Such situations include tanker loading bays and drum filling. Transfer includes loading, filling, dumping, bagging.
PROC9	Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage. This PROC can also be used to cover sampling operations.
PROC10	Roller application or brushing	This includes application of paints, coatings, removers, adhesives or cleaning agents to surfaces with potential exposure arising from splashes. This PROC can also be assigned to tasks such as cleaning of surfaces using long-handle tools.

[26] In this context “dedicated facility” means that the installation, its containment and engineering controls are specifically designed for a particular process (it does not mean it is substance or product specific).

PROC11	Non industrial spraying	Air dispersive techniques i.e. dispersion into air (= atomization) by e.g. pressurized air, hydraulic pressure or centrifugation, applicable for liquids and powders. Includes spraying of substances/mixtures for surface coating, adhesives, polishes/cleaners, air care products, blasting. The reference to 'non-industrial' is to differentiate where conditions mentioned in PROC7 cannot be met. It is not meant that the activity can only take place at non-industrial sites.
PROC12	Use of blowing agents in manufacture of foam	Use of substances to facilitate the process of production of foams by forming gas bubbles in a liquid mixture. It can be either a continuous or a batch process.
PROC13	Treatment of articles by dipping and pouring	Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; Includes handling of treated objects (e.g. from/to treatment basin, after drying, plating). The service life of the article after the treatment needs to be reported separately.
PROC14	Tabletting, compression, extrusion, pelletisation, granulation	This covers processing of mixtures and/or substances into a defined shape for further use.
PROC15	Use as laboratory reagent	Use of substances at small scale in laboratories (less than or equal to 1 l or 1 kg present at workplace). Larger operations in laboratories and R+D installations should be treated as industrial processes. This includes the use in quality control processes.
PROC16	Use of fuels	Covers the use of (solid and liquid) fuel (including additives), including transfers via the closed system, where limited exposure to the product in its unburned form is expected. Assignment of PROC 8 or PROC 9 not needed in this case. The exposure to exhaust gases is not covered.
PROC17	Lubrication at high energy conditions in metal working operations	Covers metal working processes where the lubricants are exposed to high temperature and friction e.g. metal rolling/forming processes, drilling and grinding, etc. Transfers for refilling or discharging from/to reservoirs are not covered.

PROC18	General greasing /lubrication at high kinetic energy conditions	Use of lubricant or greasing agents in high kinetic energy conditions, including manual application. It does not refer to any filling operation.
PROC19	Manual activities involving hand contact	Addresses tasks, where exposure of hands and forearms can be expected; no dedicated tools or specific exposure controls other than PPE can be put in place. Examples are manual mixing of cement and plasters in construction works or mixing of hair dyes and bleaches.
PROC20	Use of functional fluids in small devices	Includes the filling and emptying of systems containing functional fluids (including transfers via the closed system) e.g. heat and pressure transfer fluids; takes place on routine basis Example: charging and discharging of motor and engine oils, brake fluids, home appliances. Assignment of PROCs 8-9 not needed in this case.
PROC21	Low energy manipulation and handling of substances bound in/on materials or articles	Cover activities such as manual cutting, cold rolling or assembly/disassembly of material/article. It can also be used for handling/transfer of massive (metal) objects.
PROC22	Manufacturing and processing of minerals and/or metals at substantially elevated temperature	Describes the general nature of processes taking place at smelters, furnaces, refineries, ovens, excluding casting, tapping and drossing operations. When the temperature has decreased , the handling of the cool material can be covered by PROC21 or PROC26.
PROC23	Open processing and transfer operations at substantially elevated temperature	Describes certain processes taking place at smelters, furnaces and ovens: casting, tapping and drossing operations. Covers also hot dip galvanising raking of melted solids in paving and water granulation. When the temperature has decreased, the handling of the cold material can be covered by PROC21 or PROC26.
PROC24	High (mechanical) energy work-up of substances bound in /on materials and/or articles	Substantial thermal or kinetic energy applied to substance by e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding, stripping.
PROC25	Other hot work operations with metals	Welding, soldering, gouging, brazing, flame cutting.

PROC26	Handling of solid inorganic substances at ambient temperature	Transfer and handling of ores, concentrates, metals and other inorganic substances in solid (but not massive) potentially dusty form. Assignment of PROC8a, PROC8b or PROC9 not needed in this case. The handling of massive objects should be addressed with PROC21.
PROC27a	Production of metal powders (hot processes)	Production of metal powders by hot metallurgical processes (atomisation, dry dispersion).
PROC27b	Production of metal powders (wet processes)	Production of metal powders by wet metallurgical processes (electrolysis, wet dispersion).
PROC28	Manual maintenance (cleaning and repair) of machinery	Covers maintenance activities for uses where the maintenance is not already included in any of the other process categories. The category covers for example: • activities when closed systems are opened and potentially entered for cleaning • generally dedicated/separate cleaning tasks conducted on a shift or less frequent basis (e.g. between individual production batches) • removal of splashes around the machinery removal of filters or material from filters • cleaning of floors that are not directly around the machinery, but still need cleaning for instance because of dust deposition when handling a dusty product
PROC0	Other	

Descriptor list for Environmental Release Categories (ERC)

The ERC categories are designed to label the characteristics of a use based on different aspects relevant from the environmental perspective:

1. The life cycle stage at which a use takes place. The life cycle stage is associated with specific type of emissions/releases of the corresponding uses:
    - Manufacture and formulation or re-packing can be expected to take place under conditions that minimise losses to waste or waste water and maximise transfer to the next stage
    - Differentiation on whether a use is considered:
        i) taking place at (large) industrial point sources (where the general capacity to technically control emissions to air and waste water can be assumed)
        ii) widespread, and thus releases are assumed to be equally distributed across Europe, largely correlated to the number of citizens discharging into a river.
    - Differentiation on whether or not a substance enters into service life

2. The technical fate (destination) of the substance resulting from the use. It indicates whether a substance is expected to become part of an article, is consumed (by reaction) on use and/or is expected to be released to soil, water air or waste. The following aspects are considered:
    - The substance (unreacted or in reacted form) becomes part of an article (including dried/cured mixtures)[27], either because it has a function in the article or because it remains (from a preceding life cycle stage) in the article without function.
    - The substance acts as a processing aid and does not become part of an article. It is released (unreacted or in reacted form) from an industrial process (e.g. surfactant in textile finishing, solvent from spray painting) or a non-industrial use (e.g. solvents or surfactants from cleaners) to waste water, air emission, soil and/or waste.
    - The substance is meant to act as part of a functional fluid (e.g. in hydraulic, heat transfer or lubrication systems). The substance is not an integral part of an article.
    - The substance reacts on use. Its reacted form (or any other transformation product) may be emitted to the environment or may become part of an article. Depending on the speed and nature of the reaction the parent substance may no longer be available for further life cycle steps or emission to the environment. However reaction/transformation products may need to be addressed in the assessment.

3. Indoor or outdoor use of a substance indicates whether direct releases to non-industrial soil or surface water may be relevant. For articles it flags in addition that

[27] If the substance is incorporated in buildings, constructions and parts of them, they should be reported in the same way as when they are incorporated into articles

increased release from article matrix may occur due to weathering conditions.

4. Indication whether articles are used under release-promoting conditions (such as abrasion from tyres or brake pads) or where the release of substances is intended (e.g. from scented articles). Also processing of articles with abrasive techniques (e.g. sanding or high pressure de-coating) is covered under this criterion.

Table R.12- 12 below provides an overview of the Environmental release categories (ERC) available for each of the life cycle stages. Table R.12- 13 provides the full description of the environmental release categories, including their name, explanation and examples. Finally, workflows are presented that describe the decision tree for the assignment of ERCs for each of the life cycle stage[28] (See Figure R.12- 4 to Figure R.12-7)

[28] Clarification on the scope of each of the life-cycle stages is provided in Section 0.

Table R.12- 12: Overview of Environmental Release categories (ERC) available for each LCS

Please note that in Table R.12- 12 below, the ERCs are not presented in their numbering order. This is to make clearer the logic of the ERC differentiation.

Code	Name
LCS: Manufacture	
ERC1	Manufacture of the substance
LCS: Formulation or re-packing	
ERC2	Formulation into mixture
ERC3	Formulation into solid matrix
LCS: Use at industrial sites	
ERC4	Use of non-reactive processing aid at industrial site (no inclusion into or onto article)
ERC6b	Use of reactive processing aid at industrial site (no inclusion into or onto article)
ERC6a	Use of intermediate
ERC6c	Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)
ERC6d	Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article)
ERC5	Use at industrial site leading to inclusion into/onto article
ERC7	Use of functional fluid at industrial site
LCS: Widespread use by professional workers **&** LCS: Consumer use	
ERC8a	Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
ERC8d	Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor)
ERC8b	Widespread use of reactive processing aid (no inclusion into or onto article, indoor)
ERC8e	Widespread use of reactive processing aid (no inclusion into or onto article, outdoor)
ERC8c	Widespread use leading to inclusion into/onto article (indoor)
ERC8f	Widespread use leading to inclusion into/onto article (outdoor)
ERC9a	Widespread use of functional fluid (indoor)
ERC9b	Widespread use of functional fluid (outdoor)
LCS: Service life	
ERC10a	Widespread use of articles with low release (outdoor)
ERC11a	Widespread use of articles with low release (indoor)
ERC10b	Widespread use of articles with high or intended release (outdoor)
ERC11b	Widespread use of articles with high or intended release (indoor)
ERC12a	Processing of articles at industrial sites with low release
ERC12b	Processing of articles at industrial sites with high release
ERC12c	Use of articles at industrial sites with low release

Table R.12- 13: Descriptor list for Environmental Release Categories (ERC)

Code	Name	Explanation and examples
ERC1	Manufacture of the substance	
ERC2	Formulation into mixture	Applies to uses in all types of formulating industries; substance is mixed (blended) into (chemical) mixtures Examples: • formulation of paints, household cleaners, lubricants, fuels, bulk chemicals for industrial uses etc.
ERC3	Formulation into solid matrix	Applies to uses in formulating industries; substance is mixed (blended) in order to be physically or chemically bound into or onto a solid matrix Example: • formulation of stabilisers into master-batches for production of polymer pellets
ERC4	Use of non-reactive processing aid at industrial site (no inclusion into or onto article)	Examples: • Chemical processing where the substance is used as solvent for crystallisation • Production activities where the substance is used as a cleaning agent (solvent or surfactant) • Polymer moulding/casting where the substance is used as anti-set off agent
ERC5	Use at industrial site leading to inclusion into/onto article	The substance or its transformation products are included into or onto article Examples: • Use of binding agent and process regulators in paints and coatings or adhesives • Use of dyes in textile fabrics and leather products • Use of metals in coatings applied through plating and galvanizing processes • Use of plasticisers, pigments or flame retardants in article matrix or coatings on articles Covers also uses where the substance remains in the article after having previously been used as processing aid (e.g. heat stabilisers in plastic processing).

ERC6a	Use of intermediate	The substance is used in order to manufacture another substance Examples: • Use of chemical building blocks (feedstock) in the synthesis of agrochemicals, pharmaceuticals etc. • Use of cyclopentanone in the synthesis of cyclopentanol
ERC6b	Use of reactive processing aid at industrial site (no inclusion into or onto article)	The substance or its transformation product(s) are not included into or onto article; substance reacts on use Examples: • Use of bleaching agents in textile and paper industry • Use of catalysts
ERC6c	Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)	The substance is used as monomer in the production of polymers (resins, plastics (thermoplastics)) Examples: • Use of vinyl chloride monomer in the production of PVC. • Use of monomers in production of resins
ERC6d	Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article)	The substance is used as process regulator (e.g. cross-linking agents, curing agents) for polymerisation process – production of resins, thermosets, rubbers, polymers Examples: • Use of styrene in polyester production • Use of vulcanization agents in the production of rubbers • Use of catalysts

ERC7	Use of functional fluid at industrial site	The substance is used as functional fluid and does not get in contact with products; substance is contained during the use. Examples: • Use of engine and machine oils • Use of fluids in hydraulic systems and heat transfer systems Does not cover the case where a substance/mixture is an integral part of an article (e.g. batteries) Does not cover uses where • substances are used as processing aids or reactants in chemical processes (see ERC 6a to 6d) • articles are treated with processing aids (e.g. metal part cleaning or textile cleaning) (see ERC 4)
ERC8a	Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)	Applies to uses by the public at large or by professional workers Use (usually) results in release into air or the sewage system Examples: • Down the drain product like e.g. Use of detergents in fabric washing, use of machine wash liquids and lavatory cleaners, use of automotive and bicycle care products (polishes, lubricants, de-icers) • Use of solvents in paints and adhesives • Use of fragrances and aerosol propellants in air fresheners.
ERC8b	Widespread use of reactive processing aid (no inclusion into or onto article, indoor)	Applies to uses by the public at large or by professional workers Example: • Use of sodium hypochlorite in lavatory cleaners, bleaching agents in fabric washing products, hydrogen peroxide in dental care products.
ERC8c	Widespread use leading to inclusion into/onto article (indoor)	Applies to uses by the public at large or by professional workers; substance or its transformation products will be physically or chemically bound into or onto article Examples: • Use of binding agent or process regulators in paints and coatings or adhesives • Use of dyes during dyeing of textile fabrics

ERC8d	Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor)	Applies to uses by the public at large or by professional workers Examples: • Use of automotive and bicycle care products (polishes, greases de-icers, detergents), use of highly volatile solvents in paints and adhesives
ERC8e	Widespread use of reactive processing aid (no inclusion into or onto article, outdoor)	Applies to uses by the public at large or by professional workers Example: • use of sodium hypochlorite or hydrogen peroxide for surface cleaning (building materials)
ERC8f	Widespread use leading to inclusion into/onto article (outdoor)	Applies to uses by the public at large or by professional workers; substance or its transformation products will be physically or chemically bound into or onto article Example: • Use of binding agent or process regulators in paints and coatings or adhesives during application
ERC9a	Widespread use of functional fluid (indoor)	Applies to uses by the public at large or by professional workers; substance is used as functional fluid and does not get in contact with products; substance is contained during the use Example: • Use of substance in oil-based electric heaters Does not cover the case where a substance/mixture is an integral part of an article (e.g. batteries)
ERC9b	Widespread use of functional fluid (outdoor)	Applies to uses by the public at large or by professional workers; substance is used as functional fluid and does not get in contact with products; substance is contained during the use Examples: • Motor oils • Break fluids in automotive brake systems • Fluids/gases is air conditioning systems Does not cover the case where a substance/mixture is an integral part of an article (e.g. batteries)

ERC10a	Widespread use of articles with low release (outdoor)	Applies to the use of articles by the public at large or by professional workers where there is no intended release of the registered substance and where the conditions of use do not promote releases. Example: • Service life of metal, wooden and plastic construction and building materials (gutters, drains, frames, etc.) • Automotive batteries
ERC10b	Widespread use of articles with high or intended release (outdoor)	Applies to the use of articles by the public at large or by professional workers where the registered substance is intended to be released or where the conditions of use promote releases. Also applies to processing by the public at large or by professional workers where the substances included into or onto articles are released (intended or not) from/with the article matrix as a result of processing. Examples: • Service life of tyres and brake pads in trucks or cars • Substances released from articles during work at elevated temperature
ERC11a	Widespread use of articles with low release (indoor)	Applies to the use of articles by the public at large or by professional workers where there is no intended release of the registered substance and where the conditions of use do not promote releases Examples: • Non-volatile substances in flooring, furniture, toys, construction materials, curtains, footwear, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing)

ERC11b	Widespread use of articles with high or intended release (indoor)	Applies to the use of articles by the public at large or by professional workers where the registered substance is intended to be released or where the conditions of use promote releases. Also applies to processing by the public at large or by professional workers where the substances included into or onto articles are released (intended or not) from/with the article matrix as a result of processing. Examples: • Substances released from fabrics, textiles (clothing, floor rugs) during washing • Fragrance in scented articles (toys, papers, sanitary towels, …)
ERC12a	Processing of articles at industrial sites with low release	Applies to uses at industrial sites where the substances included into or onto articles are released (intended or not) from/with the article matrix as a result of processing by workers; release remains low Examples: • Cutting of textile, cutting, machining or grinding of metal or polymers in engineering industries
ERC12b	Processing of articles at industrial sites with high release	Applies to uses at industrial sites where the substances included into or onto articles are released (intended or not) from/with the article matrix as a result of processing by workers; release is high Examples: • Substances released from articles during sanding operations or paint stripping by shot-blasting (high amounts of dust expected) • Substances released from articles during processes at elevated temperature
ERC12c	Use of articles at industrial sites with low release	Applies to uses of articles at industrial sites where the substances included into or onto articles are not intended to be released and where the conditions of use do not promote release. Examples: Machinery at industrial sites Note: where an article is used at industrial sites but also in the same conditions by professional workers or consumers (e.g. pens, plates, mobile phones) there is no need to report that use with an ERC12c. That use can be reported with the ERC categories corresponding to widespread use of articles.

Figure R.12- 4: General overview and decision tree for ERC assignment for the 'manufacture' and 'formulation or re-packing' life cycle stages

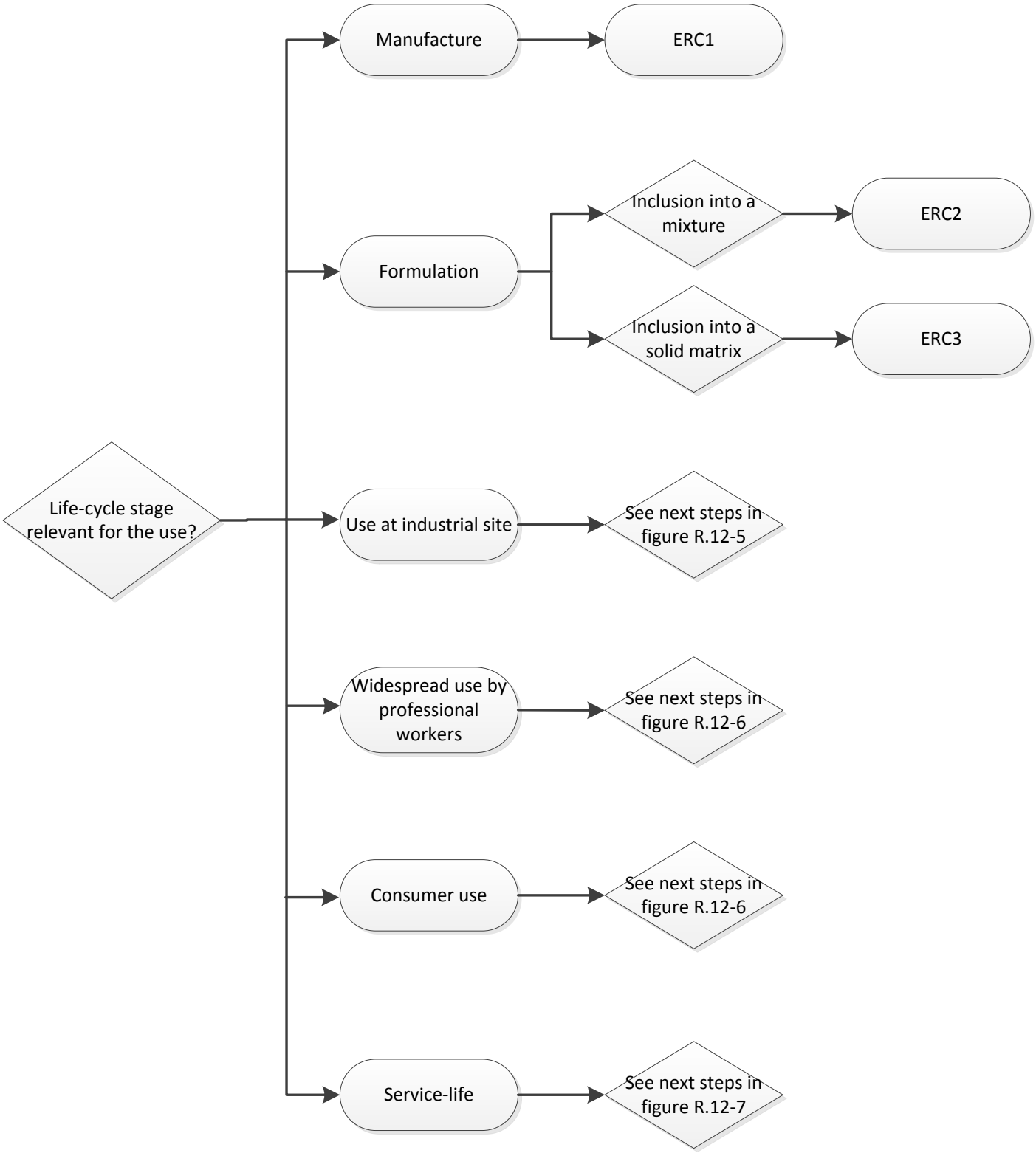


Figure R.12- 5: Decision tree for ERC assignment for the life-cycle stage 'use at industrial site'

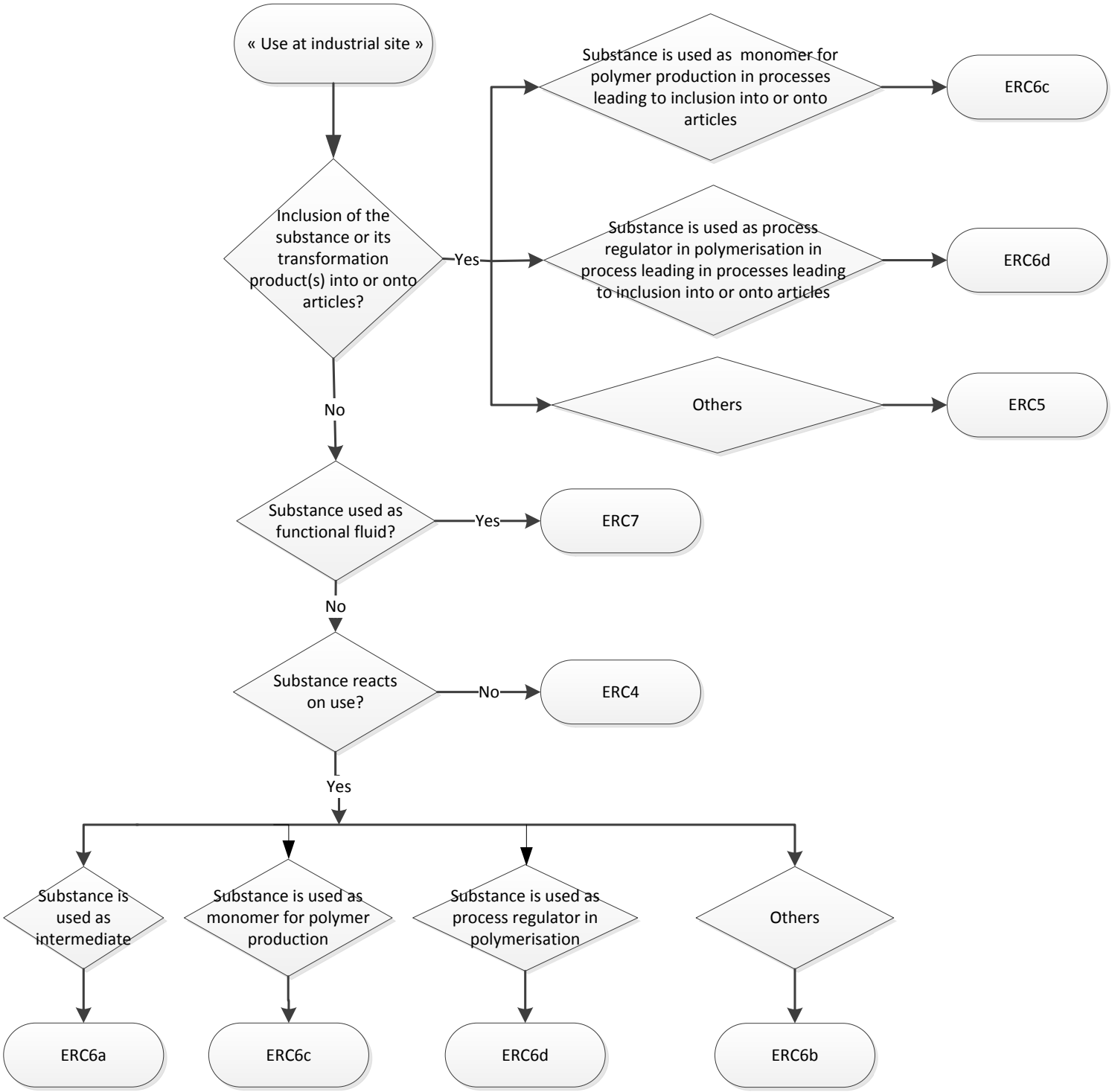


Figure R.12- 6: Decision tree for ERC assignment for the life-cycle stages 'widespread use by professional workers' and 'consumer use'

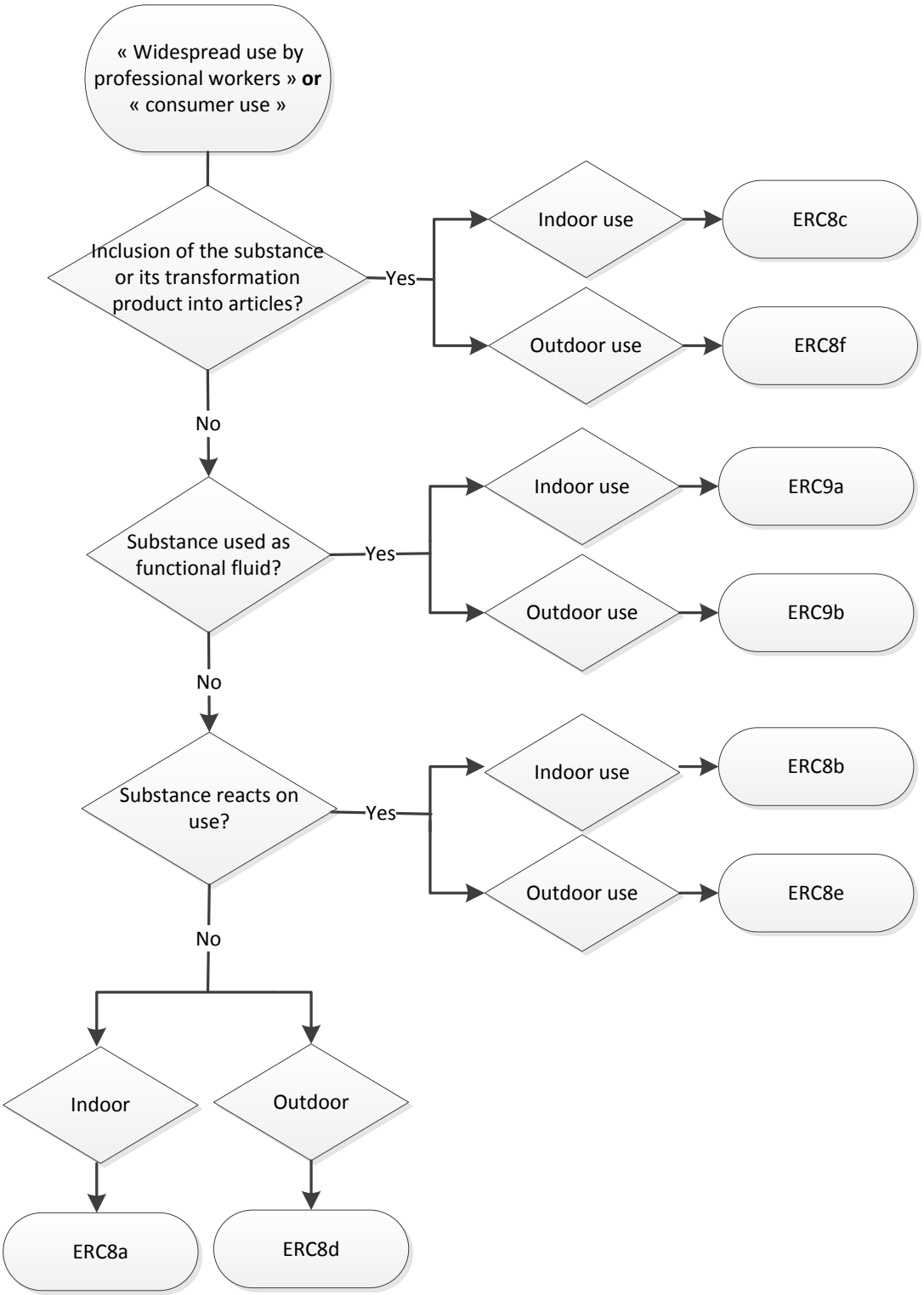
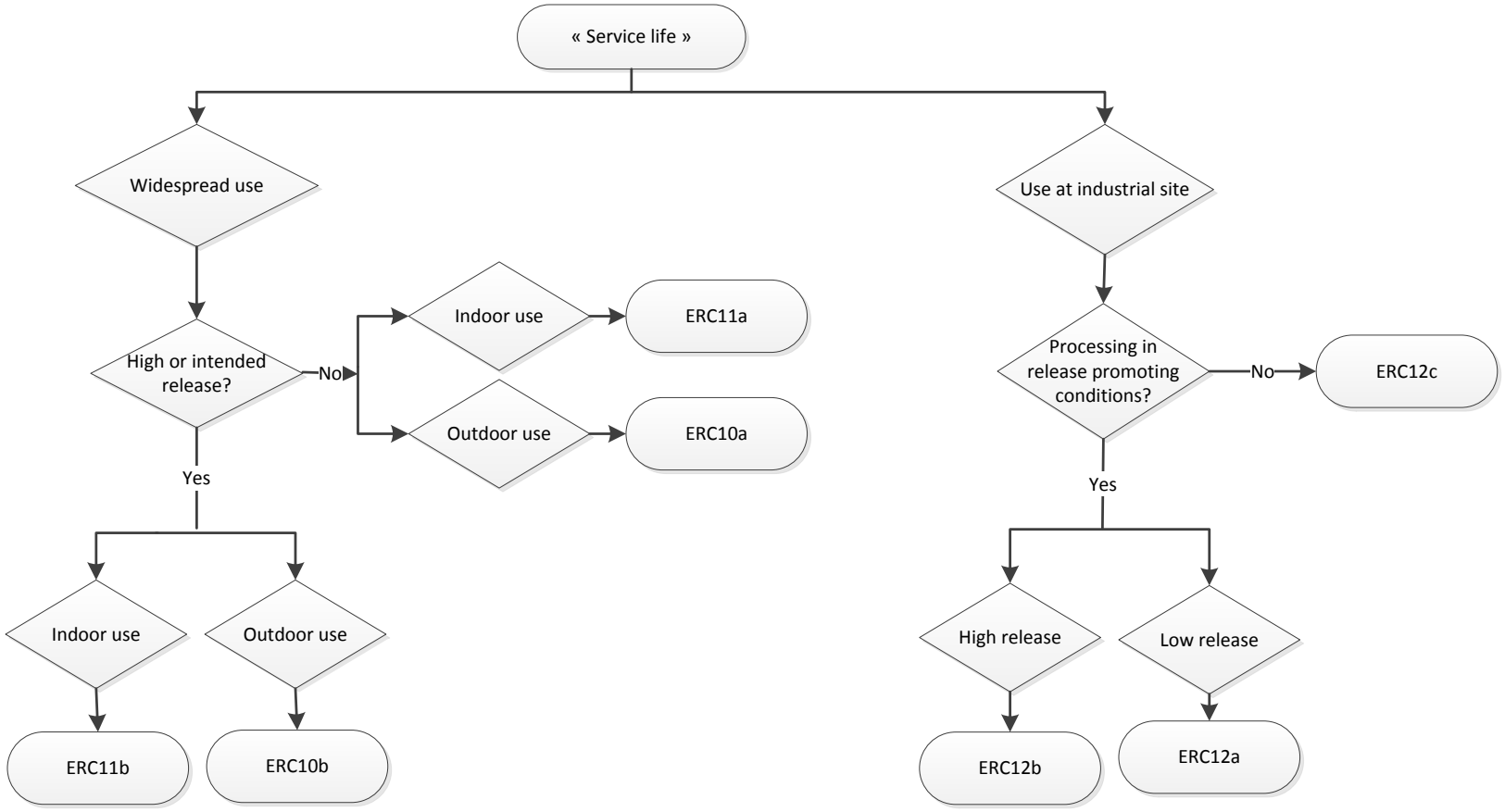


Figure R.12- 7: Decision tree for ERC assignment for the life-cycle stage 'Service life'



Descriptor list for Article Categories (AC)

The Articles Categories (AC) are designed to describe the types of article in which the substance is contained or on which the substance has been applied. This information is relevant at the service life stage where the activities of workers and consumers with articles need to be described.

The article categories are designed to label the characteristics of articles where the substances are applied or embedded based on different aspects, essentially:

- the type of material (matrix) e.g. plastic matrix, wood material, ceramics;
- type of articles defined essentially based on exposure consideration e.g. articles being similar in terms of release potential and most relevant exposure route. In particular the following drivers of exposure were considered: large surfaces, direct and intense skin contact, products for use by children (mouthing route to be considered), articles meant to get in contact with food. In some cases the categories also reflect specific regulatory framework applicable to the use of the article or to its waste stage e.g. vehicles, electrical/electronic articles, toys, batteries.

This further differentiation into article categories was also required to trigger a better description of the article type covered in the registration dossier, where, for example, the simple identification of the material was not sufficient to correctly describe the use by means of use descriptor. The ECETOC TRA consumer exposure estimation tool proposes a different differentiation into subcategories for some of the material based articles for exposure assessment purposes: these subcategories are listed and described in Chapter R.15 of the IR&CSA Guidance; cross reference between ECETOC subcategories and article categories as proposed here is also reported in Chapter R.15 of the IR&CSA Guidance.

It should be noted that even if from the article category it appears that the main potential for exposure relates to one specific route, once it comes to the assessment, registrants are expected to assess all relevant routes. Considering a route as not relevant always requires an argumentation why the exposure is likely to be absent or negligible.

If the manufacturer/importer or the downstream user is unable to identify a suitable article category in Table R.12- 14, or wishes to be more specific, the use could be described under "AC0 - other". If possible, a code (and the corresponding phrasing) from the TARIC system[29] should be selected.

Table R.12- 14: Descriptor list for Articles Categories (AC)

Code	Name	Suitable TARIC chapters	Explanation and examples
Categories of complex articles			
AC1	Vehicles	**86-89**	

[29] http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp

Code	Name	Suitable TARIC chapters	Explanation and examples
AC1a	Vehicles covered by End of Life Vehicles (ELV) directive		e.g. personal vehicles, delivery vans
AC1b	Other vehicles		e.g. boat, train, metro, planes
AC2	Machinery, mechanical appliances, electrical/electronic articles	**84/85**	
AC2a	Machinery, mechanical appliances, electrical/electronic articles covered by the Waste Electrical and Electronic Equipment (WEEE) directive		e.g. refrigerators, washing machines, vacuum cleaners, computers, telephones, drills, saws, smoke detectors, thermostats, radiators
AC2b	Other machinery, mechanical appliances, electrical/electronic articles		e.g. large-scale stationary industrial tools
AC3	Electrical batteries and accumulators	**8506/07**	
Material-based categories of articles			
AC4	Stone, plaster, cement, glass and ceramic articles	**68/69/70**	
AC4a	Stone, plaster, cement, glass and ceramic articles: Large surface area articles		Construction and building materials e.g. floor coverings, isolation articles
AC4b	Stone, plaster, cement, glass and ceramic articles: Toys intended for children's use (and child dedicated articles)		
AC4c	Stone, plaster, cement, glass and ceramic articles: Packaging (excluding food packaging)		
AC4d	Stone, plaster, cement, glass and ceramic articles: Articles intended for food contact		e.g. dinner ware, drinking glasses, pots, pans, food storage containers
AC4e	Stone, plaster, cement, glass and ceramic articles: Furniture & furnishings		
AC4f	Stone, plaster, cement, glass and ceramic articles: Articles with intense direct dermal contact during normal use		e.g. jewellery
AC4g	Other articles made of stone, plaster, cement, glass or ceramic		
AC5	Fabrics, textiles and apparel	**50-63**, 94/95	

Code	Name	Suitable TARIC chapters	Explanation and examples
AC5a	Fabrics, textiles and apparel: Large surface area articles		Construction and building materials e.g. floor or wall materials: carpets, rugs, tapestries
AC5b	Fabrics, textiles and apparel: Toys intended for children's use (and child dedicated articles)		e.g. stuffed toys, blankets, comfort objects
AC5c	Fabrics, textiles and apparel: Packaging (excluding food packaging)		
AC5d	Fabrics, textiles and apparel: Articles intended for food contact		
AC5e	Fabrics, textiles and apparel: Furniture & furnishings, including furniture coverings		e.g. sofa cover, car seat cover, fabric chair, hammock
AC5f	Fabrics, textiles and apparel: Articles with intense direct dermal contact during normal use		e.g. clothing, shirts, pants, shorts
AC5g	Fabrics, textiles and apparel: Articles with intense direct dermal contact during normal use: bedding and mattresses		e.g. blankets, sheets
AC5h	Other articles made of fabrics, textiles and apparel		
AC6	Leather articles	**41-42**, 64, 94	
AC6a	Leather articles: Large surface area articles		Construction and building materials
AC6b	Leather articles: Toys intended for children's use (and child dedicated articles)		
AC6c	Leather articles: Packaging (excluding food packaging)		
AC6d	Leather articles: Articles intended for food contact		
AC6e	Leather articles: Furniture & furnishings, including furniture coverings		e.g. sofa, car seat, chair
AC6f	Leather articles: Articles with intense direct dermal contact during normal use		e.g. clothing such as jackets, shoes, or gloves
AC6g	Other leather articles		e.g. domestic articles such as decoration articles, leather boxes

Code	Name	Suitable TARIC chapters	Explanation and examples
AC7	Metal articles	71, **73-83**, 95	
AC7a	Metal articles: Large surface area articles		Construction and building materials e.g. roof sheets, pipes,
AC7b	Metal articles: Toys intended for children's use (and child dedicated articles)		
AC7c	Metal articles: Packaging (excluding food packaging)		
AC7d	Metal articles: Articles intended for food contact		e.g. packaging containers, metal tins, knifes, cooking pots
AC7e	Metal articles: Furniture & furnishings		e.g. outdoor furniture, benches, tables
AC7f	Metal articles: Articles with intense direct dermal contact during normal use		e.g. handles, jewellery
AC7g	Other metal articles		
AC8	Paper articles	**48-49**	includes paperboard, cardboard
AC8a	Paper articles: Large surface area articles		Construction and building materials e.g. insulation panels, wall papers
AC8b	Paper articles: Toys intended for children's use (and child dedicated articles)		
AC8c	Paper articles: Packaging (excluding food packaging)		
AC8d	Paper articles: Articles intended for food contact		
AC8e	Paper articles: Furniture & furnishings		
AC8f1	Paper articles: Articles with intense direct dermal contact during normal use: personal hygiene articles		e.g. nappies, feminine hygiene products, adult incontinence products, tissues, towels, toilet paper
AC8f2	Paper articles: Articles with intense direct dermal contact during normal use: printed articles with dermal contact in normal conditions of use		e.g. newspapers, books, magazines, printed photographs
AC8g	Other paper articles		e.g. lampshades, paper lanterns

Code	Name	Suitable TARIC chapters	Explanation and examples
AC10	Rubber articles	**40**, 64, 95	Includes foam materials
AC10a	Rubber articles: Large surface area articles		Construction and building materials e.g. flooring
AC10b	Rubber articles: Toys intended for children's use (and child dedicated articles)		e.g. baby bottle nipples, soothers
AC10c	Rubber articles: Packaging (excluding food packaging)		
AC10d	Rubber articles: Articles intended for food contact		
AC10e	Rubber articles: Furniture & furnishings, including furniture coverings		
AC10f	Rubber articles: Articles with intense direct dermal contact during normal use		e.g. gloves, boots, clothing, rubber handles, gear lever, steering wheels
AC10g	Other rubber articles		
AC11	Wood articles	**44**, 94/95	
AC11a	Wood articles: Large surface area articles		Construction and building materials e.g. floor, claddings
AC11b	Wood articles: Toys intended for children's use (and child dedicated articles)		
AC11c	Wood articles: Packaging (excluding food packaging)		
AC11d	Wood articles: Articles intended for food contact		
AC11e	Wood articles: Furniture & furnishings		
AC11f	Wood articles: Articles with intense direct dermal contact during normal use		e.g. handles, pencils
AC11g	Other wood articles		
AC13	Plastic articles	**39**, 94/95, 85/86	includes foam materials
AC13a	Plastic articles: Large surface area articles		Construction and building materials e.g. flooring, insulation
AC13b	Plastic articles: Toys intended for children's use (and child dedicated articles)		includes baby-bottles

Code	Name	Suitable TARIC chapters	Explanation and examples
AC13c	Plastic articles: Packaging (excluding food packaging)		
AC13d	Plastic articles: Articles intended for food contact		e.g. plastic dinner ware, food storage
AC13e	Plastic articles: Furniture & furnishings, including furniture coverings		
AC13f	Plastic articles: Articles with intense direct dermal contact during normal use		e.g. handles, ball pens
AC13g	Other plastic articles		
AC0	Other		

Descriptor list for technical functions (TF)

The Technical Function categories (TF) are designed to describe the role that the substance fulfils when it is used (what it actually does as such in a process or what it actually does in a mixture or article). The technical function is therefore focused on substances, and it is not meant to convey information on the type of mixture or article.

Specifying the technical function of the substance as such is also required for section 1.2 of the safety data sheet for substances meeting the criteria for classification as hazardous. For this, the registrant may also make use of the technical functions listed in the table below.

Table R.12- 15: Descriptor list for Technical functions (TF)

Name	Explanation
Ablative	Substance that is applied to a substrate to protect it from heat by dissipating heat through the process of erosion, melting, or vaporization of the material.
Abrasive	An abrasive is a substance used to abrade, smooth, or polish an object. Abrasives are used to remove imperfections from a surface; used to smooth, scour, scrub, clean, wear down, or polish surfaces by rubbing against the surface; usually fine powders of hard substances. Examples include sandstones, pumice, quartz, silicates, aluminium oxides, and glass.
Absorbent	Chemical substance used to retain other substances by assimilation.
Adhesion promotor	Any substance, inorganic or organic, natural or synthetic, used to join opposite surfaces to each other, promote bonding between other substances, promote adhesion of surfaces, or fasten other materials together. They are generally applied from a solvent solution and allowed to dry on the two facing surfaces.
Adsorbent	Chemical substance used to retain other substances by accumulation on their surface; substance with a large surface area which can attract dissolved or finely dispersed substances from another medium.
Aerating and dearating agents	Substance that influences the amount of air or gases entrained in a material.
Antiadhesive	Substance that prevents or reduces the adhesion of a material to itself or to another material; prevents bonding between other substances by discouraging surface attachment; functions as the antitheses of adhesive.

Alloying element	Substances that are added to metals alloys like steel to modify its properties such as strength, hardness, or to facilitate its treatment.
Anticaking agent	Substance that prevents granular or particulate materials from sticking or caking during transfer, storage, or use.
Anticondensation agent	Substance or material that is used to avoid condensation on surfaces and in the atmosphere.
Antifreeze agent	A substance added to fluids, especially water, to reduce the freezing point of the mixture, or applied to surfaces to melt or prevent the build-up of ice. Examples of products include antifreeze liquids, windshield de-icers, aircraft de-icers, lock release agents, ice melting crystals, and rock salt.
Antioxidant	Substance that retards oxidation, rancidity, deterioration, and gum formation; used to maintain the quality, integrity, and safety of finished products by inhibiting the oxidative degradation of the ingredients in the formulation. Saturated polymers have greater oxidative stability and require relatively low concentrations of stabilizers.
Antiredeposition agent	Any substance that prevents dirt and grease from resettling on a cleaned surface or that helps keep soils from re-depositing onto clothing in the wash water after they have been removed. Antiredeposition agents are water-soluble and typically negatively charged.
Antiscaling agent	Substances added to products to prevent the build-up of inorganic oxide deposits. The formation of scale can be caused by the deposition of salts or minerals and may not necessarily lead to surface corrosion, therefore these chemicals are not corrosion inhibitors. Substances prevent the build-up or removes limescale and fouling. These substances are also called ‘Descalers’.
Antistain agent	Antistain agent is a substance that provides stain blocking and soil resistance to soft surface cleaners and protectors.
Antistatic agent	Any substance that prevents or reduces the tendency of a material to accumulate a static charge or alters the electrical properties of materials by reducing their tendency to acquire an electrical charge.
Antistreaking agent	A substance which serves to enhance evaporation or reduce film formation in order to prevent the formulation of streaks on a surface during cleaning.

Barrier (Sealant)	Material designed only to fill up a space, prevent seepage of moisture or air, passage of liquid or gas. The spaces can be joints, gaps or cavities that occur between two substrates.
Binder	Any cementitious material that is used to hold dry powders or aggregate together; added to compounded dry powder mixtures of solids to provide adhesive qualities during and after compression to make tablets or cakes; is soft at high temperatures and hard at room temperature.
Biocide	Substance intended for preventing, neutralizing, destroying, repelling, or mitigating the effects of any pest or microorganism; that inhibits the growth, reproduction, and activity of organisms, including fungal cells; decreases the number of fungi or pests present; deters microbial growth and degradation of other ingredients in the formulation.
Bleaching agent	A bleaching agent is a material that lightens or whitens a substrate through chemical reaction. The bleaching reactions usually involve oxidative or reductive processes that degrade colour systems. Bleaching and decolourization can occur by destroying one or more of the double bonds in the conjugated chain, by cleaving the conjugated chain, or by oxidation of one of the other moieties in the conjugated chain.
Brightener	Substance that is used to brighten, whiten, or enhance the appearance of colour of fabric and paper, usually by absorbing light in the ultraviolet and violet region (340-370 nm) of the electromagnetic spectrum, and re-emitting light in the blue region (420-470 nm). This causes a "whitening" effect by increasing the overall amount of blue light reflected. Optically colourless on the substrate and do not absorb in the visible part of the spectrum.
Catalyst	Substances that increase the efficiency of a chemical reaction e.g. reaction needs less energy. Catalysts take part in the reaction but are not consumed during the process.
Chain transfer agent	Substance that terminates the growth of a molecular chain and forms a new radical that can act as the initiator for a new chain.

Chelating agent	A substance that has the ability to complex with inactivate metallic ions; used to remove ions from solutions and soils by forming a type of coordination complex so that the ions usual precipitation reactions are prevented; material that cleans oxide films from metals by stabilizing metal ions through complexing heterocyclic rings around each ion. They contain two or more electron donor atoms that can form coordinate bonds to a single metal atom. After the first such coordinate bond, each successive donor atom that binds creates a ring containing the metal atom; this cyclic structure is called a chelation complex or chelate.
Cleaning agent	Substance or material used to remove dirt or impurities from surfaces; acts to loosen and remove dirt and grease from surfaces.
Cloud-point depressant	Substance that depresses the temperature at which solids begin to separate from a liquid, at a temperature lower than that normally allowed.
Coalescing agent	Ingredients that decrease the minimum film-forming temperature (MFT) and, upon evaporation, yield a hard film. In polishes, the most common coalescing agent is glycol ether however, pyrrolidines and benzoates are also used.
Compatibilizer	Enables a reaction between two or more dissimilar polymers, allowing them to become more intimately mixed than before.
Conductive agent	Material used to conduct electrical current.
Corrosion inhibitor	Chemical substance used to prevent or retard corrosion metallic materials. They are needed in many products packaged in metal containers (such as aerosol products) and also used in such products as lubricants and other metal treatment products to provide protection to the substrates or surfaces on which the lubricants are used.
Crystal growth modifiers (nucleating agents)	Substance used to reduce or increase crystal growth.
Deflocculant	Substance used to fluidize concentrated slurries to reduce their bulk viscosity or stickiness in processing or handling.

Defoamer	Chemical that is used to control foam; prevents foam from forming; breaks down any foam that does form; reduces foaming from proteins, gases, or nitrogenous materials. They reduce the tendency of finished products to generate foam on shaking or agitation. The ability of a material to act as an antifoam depends on its tendency to concentrate on the surface of existing or forming bubbles and to disrupt the continuous films of liquid surrounding them. As process aid, it improves filtration, dewatering, washing, and drainage of many types of suspensions, mixtures, and slurries.
Demulsifier	Substance used to destroy an emulsion or prevent its formation.
Density modifier	Substance that modifies the density of a material.
Deodorizer	Substance that reduces or eliminates unpleasant odour and protects against the formation of malodour on body surfaces. Counteraction, sometimes referred to as neutralization, occurs when two odorous substances are mixed in a given ratio and the resulting odour of the mixture is less intense than that of the separate components.
Diluent	Substance that serves primarily to reduce the concentration of the other ingredients in a formulation; volatile liquid that is added to modify the consistency or other properties. The term is most often used for liquid formulations, with the term filler used for solid or powder formulations.
Dispersing agent	Substance added to a suspending medium or suspension to improve the separation of particles; to ensure proper dispersion; to prevent settling or clumping; to encourage uniform and maximum separation of individual, extremely fine solid particles or liquid droplets, often of colloidal size. A typical use is dispersal of dyes to ensure uniform coloration.
Drier	These substances, which speed the drying of paint, ink, etc., are often organometallic compounds.
Durability agent	Durability agents are ingredients added to increase the durability and therefore the functional life of a material.
Dust suppressant	Substance used to control finely grained solid particles to reduce their discharge into the air.
Dusting agent	Substance that is dusted onto the surface of a material (e.g., rubber) to reduce surface tack.

Dye	Substance used to impart colour to other materials or mixtures; added to a material to add colour; soluble. Molecularly dispersed within a liquid, transferred to a material, and bound to that material through intermolecular forces. Typically an organic substance, although exceptions do exist. A dye requires some degree of solubility that allows it diffuse into the polymeric matrix of a textile fibre.
Elasticizer	Substance that increases the elasticity of a material.
Embalming agent	Substance used for the preservation of biological tissue.
Energy releasers (explosives, motive propellant)	Substance characterized by chemical stability, but may be induced to undergo rapid chemical change without an outside source of oxygen, rapidly producing a large quantity of energy and gas accompanied by a large increase in volume and an explosion, bursting, or expansion.
Etching agent	Etching Agent is a substance that removes unprotected areas of metal or glass surfaces. Etching agents are usually acids or bases.
Explosion inhibitor	Substance used to reduce the explosion potential of flammable materials.
Fertilizers (soil amendments)	Chemical substance used to increase the productivity and quality of farm crops, including plants, animals, and forestry; added to soil to supply chemical elements needed for plant nutrition.
Filler	Ingredient added to fill out a dry product formulation and to lower the concentration of other ingredients; used to provide bulk, increase strength, increase hardness, or improve resistance to impact; used to extend a material and to reduce its cost by minimizing the amount of more expensive substances used in the production of articles; used to fill cavities or tighten joints; relatively inert and normally non-fibrous, finely divided substance added usually to extend volume and sometimes to improve desired properties, such as whiteness, consistency, lubricity, density or tensile strength.
Film former	Any component of a material that aids the material in forming a thin continuous sheet on its substrate. This sheet will act as a barrier between the environment and its substrate. Silicone is a good film-former in furniture polishes because of its ease of application, soil removal, and depth of glossiness. Polymers are the most commonly used film formers.
Finishing agents	Chemical substances used to impart such functions as softening, staticproofing, wrinkle resistance, and water repellence. Substances may be applied to textiles, paper, and leather.

Fire extinguishing agent	Any agent incorporated or applied to slow down combustion once started; Removes heat faster than it is released; separates the fuel and oxidizing agent; dilutes the vapour phase concentration of the fuel and oxidizing agent below what is needed for combustion.
Fixing agent (mordant)	Substance used to interact with a dye on fibres to improve fastness.
Flame retardant	Flame retardation is a process by which the normal degradation or combustion processes of polymers have been altered by the addition of certain chemicals. They are substances used on the surface of or incorporated into combustible materials to reduce or eliminate their tendency to ignite when exposed to heat or a flame for a short period of time; used to raise its ignition point; used to slow down or prevent combustion.
Flocculating agent	A flocculating agent is a chemical or substance that facilitates flocculation of suspended solids in liquid. Flocculating agents are chemical additives, which, at relatively low levels compared to the weight of the solid phase, increase the degree of flocculation of a suspension. They act on a molecular level on the surfaces of the particles to reduce repulsive forces and increase attractive forces. The principal use of flocculating agents is to aid in making solid–liquid separations.
Flotation agent	Substance used to concentrate and obtain minerals from ores.
Flow promoter	Substance that reduces drag in fluids in motion and between a fluid and a conduit surface.
Flux agent	Substance used to promote the fusing of minerals or prevent oxide formation; for casting or joining materials.
Foamant	Any substance that promotes or enhances formation of a lather or foam (i.e., a dispersion of a gas in a liquid or solid); used to form physically, by expansion of compressed gases or vaporization of liquid, or chemically, by decomposition evolving a gas, a foam or cellular structure in a plastic or rubber material.
Food flavouring and nutrient	Substance used in food or animal feedstuffs to produce or enhance taste or odour or nutritional value. Flavour compounds are molecules that stimulate the human taste chemical senses.
Fragrance	Chemical substances used to impart control odours or impart pleasing odours. Fragrance compounds are molecules that stimulate the human olfactory chemical senses.

Freeze-thaw additive	These synthetic resin emulsions or synthetic lattices enable paints, coatings, and other products to retain original consistency and to resist coagulation when exposed to freezing and thawing prior to application.
Friction agent	Materials used to enhance friction between two objects.
Fuel	Chemical substance used to create mechanical or thermal energy through chemical reactions; used to evolve energy in a controlled combustion reaction.
Fuel additive	Substances added to a fuel for the purpose of controlling the rate of reaction or limiting the production of undesirable combustion products; provide other benefits such as corrosion inhibition, lubrication, or detergency.
Gelling modifier	Substance that influences the formation or destruction of a gel.
Hardener	Increases the strength, hardness, and abrasion resistance of coatings, adhesives, sealants, elastomers, and other products
Heat stabilizer	Substance that protect polymers from the chemical degrading effects of heat or UV irradiation.
Heat transferring agent	Substance used to transmit or to remove heat from another material.
Humectant	Humectant is a substance that is used to retard moisture loss from the product during use. This function is generally performed by hygroscopic materials. The efficacy of humectants depends to a large extent on the ambient relative humidity.
Hydraulic (functional) fluids	Liquid or gaseous chemical substances used for transmitting pressure and EP-additives. Transfer power in hydraulic machinery.
Impregnation agent	Substance used to admix with solid materials, which retain their original form.
Incandescent agent	Substance that is used to emit electromagnetic radiation at high temperature.
Insulators	Substances used to prevent or inhibit the flow of heat, electrical current, light, and the transmission of sound between two media. (acoustic, electrical, and thermal insulators).

Intermediate (precursor)	Chemical substances consumed in a reaction in order to manufacture other chemical substances at an industrial processing facility.
Ion exchange agent	Chemical substances, usually in the form of a solid matrix, that are used to selectively remove targeted ions from a solution. In ion exchange, ions of a given charge (either cations or anions) in a solution are adsorbed on a solid material (the ion exchanger) and are replaced by equivalent quantities of other ions of the same charge released by the solid.
Leaching agent	Substance that, when added to a solvent, aids in the dissolution of a component of an insoluble solid mixture.
Lubricating agent	Substance introduced between two moving surfaces or adjacent solid surface to reduce the friction between them, improve efficiency, reduce wear, and reduce heat generation; enhance the lubricity of other substances. These lubricating films are designed to minimize contact between the rubbing surfaces and to shear easily so that the frictional force opposing the rubbing motion is low.
Luminescent agent	Substance that emits visible radiation upon absorption of energy in the form of photons, charged particles, or chemical change.
Magnetic element	Substance added into materials in order to make them magnetic.
Monomers	Substance usually containing carbon and of a low molecular weight and simple structure which is capable of conversion to polymers, synthetic resins, or elastomers by repetitive combination with itself or other similar molecules.
No technical function	To be used in the cases where the substance does not fulfil any particular technical function during the use described (e.g. case where a processing aid remains in the matrix of an article without fulfilling any technical function during service life)
Opacifier	Substance that renders solutions opaque; reduces transparency or the ability of light to pass through solution; added to finished products to reduce their clear or transparent appearance.
Oxidizing agent	Oxidizing agent is a substance that gains electrons during their reaction with a reducing agent. Oxidizing agents commonly contribute oxygen to other substances.

pH regulating agent	Maintains the desired pH range of a substance; used to alter, stabilize, or control the pH (hydrogen ion concentration). Substances used to alter or stabilize the hydrogen ion concentration (pH).
Photochemical	Chemical substance used for its ability to alter its physical or chemical structure through absorption of light, resulting in the emission of light, dissociation, discoloration, or other chemical reaction; used to create a permanent photographic image.
Pigment	Any substance, usually in the form of a dry powder, that imparts colour to another substance or mixture by attaching themselves to the surface of the substrate through binding or adhesion; may contribute towards opacity, durability, and corrosion resistance. Must have positive colorant value; larger than molecular particle size and held in place by corresponding low mobility; scatter and absorb light. Pigments differ from dyes in that they are insoluble in the vehicle and exist as dispersed compounds in paint rather than as a solute.
Plasticizer	An organic compound that softens synthetic polymers; added to a high polymer to facilitate processing and to increase flexibility, plasticity, fluidity and toughness of the final product by internal modification (solution) of the polymer molecule. Plasticizers may be added internally or externally. A rigid polymer can also be externally plasticized by addition of a plasticizer, which imparts the desired flexibility but is not chemically changed by reaction with the polymer.
Plating agent	Substances/materials used as a source for a layer of metal deposited on another surface, or that aid in such a deposition. These are used in processes such as electroplating, galvanization or coating.
Pressure transfer agent	Lubricating oil and grease additive that prevents metal to metal contact at high temperatures or under heavy loads where severe sliding conditions exist. Functions by reacting with the sliding metal surfaces to form oil-insoluble surface films.
Process regulator	Chemical substance used to change the rate of a chemical reaction, start or stop the reaction, or otherwise influence the course of the reaction. May be consumed or become part of the reaction product.
Processing aid	Chemical substances used to improve the processing characteristics or the operation of process equipment or to alter or buffer the pH of the substance or mixture, when added to a process or to a substance or mixture to be processed. Processing agents do not become a part of the reaction product and are not intended to affect the function of a substance or article created.

Propellants, non-motive (blowing agents)	Substance that is used for expelling products from pressurized containers (aerosol products); used to dissolve or suspend other substances and either to expel those substances from a container in the form of an aerosol or to impart a cellular structure to plastics, rubber, or thermo set resins; provides the force necessary to expel the contents of aerosol containers; liquefied or compressed gas within which substances are dissolved or suspended and expelled from a container upon discharge of the internal pressure through expansion of the gas. The formulated product in the pressurized container may be solution, emulsion, or suspension.
Reactive cleaning/removal agent	Substance that reacts with and removes surface contaminants and is generally consumed, e.g., oxides, sulfides.
Reducing agent	Substance that during reactions with oxidizing agents lose electrons; commonly contributes hydrogen to other substances; used to remove oxygen, hydrogenate or, in general, acts as electron donor in chemical reactions.
Refrigerants	Substances used within machines such as air conditioning units, refrigerators, and walk in freezers to cool indoor air and reduce temperatures.
Resins (prepolymers)	Usually high molecular weight polymers that lower viscosity. Thermoplastic resins soften when exposed to heat and return to original form at room temperature, and thermosetting resins solidify irreversibly when heated due to cross-linking.
Semiconductor and photovoltaic agent	Substance that has resistivity between that of insulators and metals; usually changeable by light, heat or electrical or magnetic field; generates electromotive force upon the incidence of radiant energy.
Sizing agent	Substance applied to substrates such as fabric, yarn, paper products, or plaster to increase abrasive resistance, stiffness, strength, smoothness, or reduce absorption.
Softener	Substance used for softening materials to improve feel, to facilitate finishing process, or to impart flexibility or workability; used in textile finishing to impart superior "hand" to the fabric and facilitate mechanical processing; has the capability of imparting softness and pliability to washable textile fabrics.
Solids separation (precipitating) agent	Chemical substances used to promote the separation of suspended solids from a liquid.

Solubility enhancer	A chemical additive that prevents chemicals or materials from separating or falling out of solution. Solubility enhancers are often used in concentrated formulations.
Solvent	Any substance that can dissolve another substance (solute) to form a uniformly dispersed mixture (solution) at the molecular or ionic size level; provides dissolving capability required for a stable formulation; dissolves certain components of the formulation to aid dispersion of components; aids oil cleansing power and controls film drying rate; allows the product to solubilize soils on surfaces and facilitate removal; used to dissolve, thin, dilute, and extract.
Stabilizing agent	A substance that tends to keep a compound, solution, or mixture from changing its form or chemical nature; renders or maintains a solution, mixture, suspension, or state resistant to chemical change; used to prevent or slow down spontaneous changes in and ageing of materials.
Surface modifier	Substance that may be added to other ingredients to adjust the optical properties associated with the surface of a material. These substances are designed to affect the luster, increase gloss, and alter the reflectance exhibited by a surface.
Surfactant	A surface active agent (surfactant) which, when added to water, causes it to penetrate more easily into, or to spread over the surface of another material by reducing the surface tension of the water (see detergent).
Swelling agent	Substance added to a material to cause that material to increase in volume and become softer.
Tackifier	Provides stickiness
Tanning agent	Substance used for treating hides and skins.
Terminator/Blocker	Substance that reacts with the end of a growing polymer chain, stopping further polymerization (terminator) or a substance used to protect a reactive moiety on a precursor during organic synthesis of a product that is subsequently removed regenerating the reactive moiety (blocker).

Thickener/Thickening agent	Any of a variety of hydrophilic substances used to increase the viscosity of liquid mixtures and solutions and to aid in maintaining stability by their emulsifying properties. Four classifications are recognized: 1) Starches, gums, casein, gelatin and phycocolloids; 2) semisynthetic cellulose derivatives (e.g. carboxymethyl-cellulose); 3) polyvinyl alcohol and carboxy-vinylates (synthetic); and 4) bentonite, silicates, and colloidal silica.
Tracer	Substance that possesses a readily detectable radioactive/isotopic label or chemical moiety which is added to biological/environmental media or chemical reactions to elucidate the transformation/transportation processes that are occurring.
UV stabilizer	Substance that protects the product from chemical or physical deterioration induced by ultraviolet light; absorbs UV radiation, thereby protecting varnishes and pigments against UV degradation.
Vapour pressure modifiers	Substance added to a liquid to modify its vapour pressure (e.g., to reduce evaporation).
Vehicle (carrier)	The vehicle dissolves or disperses solid components of a substance, allowing even dispersion throughout application. The vehicle carries the other particles within a substance.
Viscosity modifier	Substance used to alter the viscosity of another substance; used to decrease or increase the viscosity of finished products; used to modify the flow characteristics of other substances, or mixtures, to which they are added; controls the deformation or flow ability of a wax product. Resins generally lower viscosity while thickeners (e.g., gums and hydroxyethyl cellulose) increase viscosity.
Waterproofing agent	A water repellent material functions by lowering the surface energy to protect surfaces against water by making water bead.
X-Ray Absorber	Substance use to block or attenuate X-rays.
Other	

Appendix R.12.5. How to manage changes

Introduction

This appendix aims to assist companies that have carried out data collection and reporting on uses based on the guidance and use descriptor pick-lists in earlier versions of the current guidance. The following sections address the changes introduced in the guidance including those in the list of use descriptors one by one, describing what they consist of, who could be affected and how the transition could be handled, including data migration considerations. The extent to which companies will be impacted by these changes largely depends on the different companies/sectors.

Update obligations and adaptation period

The update of this guidance as such does not trigger a requirement to update existing registration dossiers. It is up to the registrant or consortium to decide which changes in the guidance should be followed up and at which point in time[30].

It should also be noted that the guidance update aims at a long term improvement of the use information and its harmonisation in the supply chain. Adjusting the existing registration dossiers and safety data sheets (where needed) to the updated guidance is expected to take place over an adaptation period, thus “old” and “new” terms will co-exist for a few years.

Different situations may exist with different priority in terms of decision to update:

- New registrations being prepared at the time of publication e.g. in view of 2018 registration deadline: registrants of substances being registered for the first time may decide to follow the updated guidance from the beginning.
- Existing registrations which have to be updated because of an external request from authorities such as the outcome of an Evaluation process. These updated dossiers are expected to follow the updated guidance when the update takes place after the publication.
- Existing registrations where the registrant(s) decide to spontaneously update the dossier. This may be triggered by:
  - new registrants joining existing joint submissions with additional uses to be covered
  - the changes in the guidance have an impact on the outcome of the chemical safety assessment e.g. clarification of the scope of some PROCs, and hence the assessment may need to be updated.
  - registrants may realise (in particular if sectors provide them with updated sector use maps) that the clarifications brought about by the updated R.12 guidance may be important for DU to clearly understand the scope of the uses covered in an exposure scenario.
  - In addition, the clarifications in this guidance as well as the improved data structure to describe uses in IUCLID6 will provide an opportunity to registrants to improve the use information in their dossiers. This will improve the basis for authorities for deciding on whether or not to select substances/dossiers for further scrutiny or regulatory risk management. On the basis of the above consideration, companies may decide to proactively (spontaneously) update their dossiers. It is recommended to give priority to cases where the substances are already under scrutiny e.g. substances listed in the Public Activities Coordination Tool (PACT)[31], the Registry of intentions[32] or the community rolling action plan (CoRAP)[33].

[30] It is recommended that once an update of the registration dossier is undertaken, it should be communicated within the joint registration as the use information is to be provided by each individual registrant within the joint registration. This will avoid that substances that are being supplied for the same uses by different registrants are described in different ways, which may lead to confusion for DU and authorities.

[31] http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

- Existing registrations with no immediate need for update: in these cases the update may be postponed to a later stage.

In any case, once such a decision to update is taken, proactive communication in the supply chain is advised. This can be done by indicating in the extended SDS, or the sector use maps, etc. that they are based on the version 2.0 (or 2010) Guidance, or on the latest update version 3.0 (or 2015) Guidance.

The following paragraphs provide some considerations on how to manage the impact brought by specific changes in the guidance.

Clarification of concepts

A number of concepts and terms are introduced in the Guidance for the first time e.g. contributing activities (CA)/contributing scenarios (CS), but they have been used already in the past years. These concepts are to some extent already well-known in supply chains; however some educational efforts may have to be made to ensure a harmonised approach across registrants. The development of use maps where the new concepts are already introduced may support the understanding by different actors.

Introduction of the Life cycle stage as a new use descriptor and removal of the main user groups (SU3/SU21/SU22) and SU10

The life-cycle stage, even though introduced as a "new" use descriptor, has been present and used already in a number of tools for some time e.g. IUCLID, guidance on exposure scenario structured short titles[34], etc.

All the registration dossiers available in the REACH database already apply this concept. As in the current version of IUCLID (IUCLID 5.4), the section on use description follows the life-cycle stages structure. Therefore, no impact is expected for existing registration dossiers.

However, company systems may be relying on these now-obsolete SUs to convey this information further downstream. The update of the existing company systems and their associated communication tools to the Life cycle stage is expected to take place gradually. The implementation of initiatives under the CSR/ES Roadmap[35] such as the improved sector use maps, or the exposure scenario structured short titles that rely on the Life cycle stage concept will help in the transition.

A fully automated assignment of the life-cycle stage descriptor can be done for each use based on information generally available on the ERCs, and the main sectors of use, as a first step. Such an automated assignment has previously been done on a large scale as all the registration dossiers available in the REACH database in the IUCLID 5.3 were upgraded to IUCLID 5.4. in 2012. A temporary creation of additional main user groups in company systems to cover all LCS may support companies in the transition, as this will allow an automatic migration to the new use descriptor in due course. Companies may choose to create SU00 for manufacture and SU99 for service life. SU10 Formulation should also be one of the 'main user groups'.

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[32] http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions

[33] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

[34] Developed in the context of the *CSR/ES Roadmap* (available at: http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/StructuredShortTitles04112014.pdf)

[35] http://echa.europa.eu/csr-es-roadmap

The following table gives an indication on how the life-cycle stage can be assigned based on existing information, and it may be useful to support the adaptation of existing systems in companies and educate downstream users in the equivalence.

Table R.12- 16: advice on assignment of LCS based on existing information

Main user groups (version 2.0, 2010)[36]	Use descriptor considerations	Corresponding Life-cycle stage(s) (version 3.0, 2015)
Temporary solution to create SU00 - Manufacture	ERC1	Manufacture (M)
SU10 – Formulation	ERC2/ERC3	Formulation or repacking (F)
SU3-Industrial uses	ERC1	Manufacture (M)
	ERC2 / ERC3	Formulation or repacking (F)
	ERC4-ERC7	Use at industrial sites (IS)
	ERC 12	Service-life (SL)
SU22 – Professional uses	ERC8-9 No ACs reported	Widespread use by professional workers (PW)
	ERC10-11 ACs reported	Service-life (SL)
SU21 – Consumer uses	ERC8-9 No ACs reported	Consumer use (C)
	ERC10-11 ACs reported	Service-life (SL)

[36] Note that the sector of uses codes presented in this column are removed from the updated use description system as they become redundant with the information provided in the life-cycle stage.

Main user groups (version 2.0, 2010)[36]	Use descriptor considerations	Corresponding Life-cycle stage(s) (version 3.0, 2015)
Temporary solution to create SU99 - Service life	ERC10-12 ACs reported	Service-life (SL)

New names of use descriptors

The names of some life cycle stages, PCs, PROCs and ERCs have been modified in order to better reflect their scope and clarify upfront some potential ambiguities which have been observed in the past.

These changes in the names are expected to have only a limited impact on existing systems as the references to the use descriptor codes remain unchanged. Dossiers should be revised only to the extent the scope of the descriptors had been misunderstood before and it only became obvious following this clarification.

Removed PC19: intermediate (covered by Technical function)

The migration of uses currently including PC 19 is expected to take place by removing the PC19 from the PC list, and assigning the Technical Function to 'Intermediate (precursor)'. In case a TF was originally selected, the TF 'intermediate (precursor)' will be added.

This change is not expected to trigger an immediate need for an update to a registration dossier, unless it is realised that the substance was incorrectly identified as an 'intermediate'[37]. Registrants may find useful to revisit their dossiers to clearly flag the regulatory status of this use as an 'intermediate' and give indication on the tonnage for that use.

New PC for hydraulic fracturing

A new PC41 'oil and gas exploration or production products has been added to enable companies to explicitly report the use of these products. As this is a new PC, there is no impact or migration needed. Companies will be able to use this PC in their registration dossiers when it is implemented in IUCLID6.

PROCs names and explanations adapted to clarify their scope

The PROCs' names and explanations have been adapted to clarify their scope. In addition, a new PROC has been added to cover the manual maintenance (cleaning and repair) of machinery to ensure that, where relevant, registrants can describe the conditions for safe use during these activities and to inform their downstream users accordingly.

There are no migration considerations as the PROCs' list has not changed.

The clarifications in the definitions of the PROCs may have an impact in cases where the exposure estimates for the assessment have been obtained using the ECETOC TRA on the

[37] See Practical Guide 16 on intermediates: http://echa.europa.eu/practical-guides

basis of an incorrectly assigned PROC. An update may be necessary, as this information can have a consequence for the chemical safety assessment (e.g. exposure estimates are no longer appropriate, and therefore the resulting risk management measures may not be adequate).

No adaptation is needed for the new PROC (PROC28). Companies will be able to use this PROC in their registration dossiers when it is implemented in IUCLID6. There is no need to add this PROC if the existing assessments are considered to cover maintenance. The use of this new PROC is expected to be relevant mainly in cases where the cleaning or maintenance activities may lead to significantly higher exposure than during other activities contributing to a use, and therefore specific risk management measures need to be put in place.

Clarification of the applicability of ERCs and the addition of a new ERC to cover the use of articles at industrial sites with low release

The ERCs' names and related explanations have been adapted to clarify their scope. An additional ERC has been included in the new version on request of the stakeholders to address the use of articles in industrial sites where low release is expected.

There are no migration considerations as the ERCs' list has not changed.

As for the PROCs, some registrants may realise that they had not assigned the proper ERC in their existing registration.

No adaptation is needed for the new ERC. Companies will be able to use this ERC in their registration dossiers when implemented in IUCLID.

Enhancing the concept of AC sub-categories to bring more specific information on articles

Additional article sub-categories have been systematically added to the article categories to provide registrants and downstream users with an opportunity to flag specific aspects of the articles in which their substances end up in. This will help authorities in understanding better the potential Service life of the substance and in particular the potential risks due to exposure or release.

These AC sub-categories are subject to a harmonisation initiative at global level in the context of the OECD[38].

The overarching (mostly material based) categories are maintained and more specific levels have been added. Where article categories were initially assigned, migration should be done to the corresponding overarching category, therefore no impact is foreseen. It is then up to the registrant to update their dossiers if they want to specify one or several of the more specific second level entries.

[38] At the time of the Guidance consultation, this proposal was subject to commenting at OECD level. The final list is to be aligned according to the result of the OECD process. Aligning these categories at OECD level will help globally acting industries in their information systems to collect and report use and exposure information such as in the process of regulatory compliance. It will also help to identify and compare existing exposure information e.g. releases from articles.

Adaptation of the categories for Technical functions (TFs) on the basis of the US EPA proposal for OECD harmonised categories

The categorisation approach for technical functions has been enhanced to bring more specific information, in line with the system for global harmonisation proposed at OECD level[36]. At the same time, it is expected that having a larger variety of TFs will help registrants to select the most appropriate option, thereby limiting the use of the free text field 'other' (which has been used substantially in the previous registration phases).

The selection of a technical function of a substance in a use does generally not have an immediate impact in the chemical safety assessment of that use. Therefore the impact in this case is expected to be minimal.

Company safety data sheet systems may be adapted to include this list of harmonised technical functions at global level.

Dossiers containing the TFs available in version 2.0 of this guidance will be migrated to the equivalent entry if identical by ECHA. Entries that were previously using the free text field can now be updated to select the corresponding entry in the pick-list. This is not meant to be a trigger for updates in itself but it may be taken into account if the dossier is going to be updated for other reasons.

ECHA's migration of the registration database will not carry out a comparison of the free texts to migrate them to corresponding structured entries, all existing free text entries will remain as free text in IUCLID6.

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