4th Meeting of the Exchange Network on Exposure Scenarios, 16-17 May 2013, Helsinki

Subject:	DISCUSSION AT ENES 4 ON THE PROPOSAL FOR HARMONISATION OF EXPOSURE SCENARIO SHORT TITLES
Prepared by:	**Paper jointly prepared by ECHA – Cefic – DUCC – ESCOM group as input to ENES 4 meeting**
Action:	

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DISCUSSION AT ENES 4 ON THE PROPOSAL FOR HARMONISATION OF

EXPOSURE SCENARIO SHORT TITLES

For use in tables of content of SDS annexes

Paper jointly prepared by ECHA – Cefic – DUCC – ESCOM group as input to ENES 4 meeting

2 May 2013

REQUEST TO ENES 4 PARTICIPANTS

Participants to the ENES 4 meeting are asked:

1. To read the document entitled 'Proposal for harmonisation of exposure scenario short titles' and the examples provided in appendix to that paper, and to send their comments on:

    a. the example under the paragraph 'implications'

    b. the 'proposed guiding rules for building and structuring ES short titles'

    c. the examples in Appendix 1;

2. To test the proposed guiding rules on their own ES examples and send these examples with conclusions to the ENES Coordination Group using the table format of Appendix 1;

3. To respond to the specific questions listed below.

Please send your feedback by 10 May to: sylvie.lemoine@aise.eu

If you are interested to present your examples of ES Short titles at the meeting, please let us know as well.

Receiving your feedback early will enable the ENES Coordination group to organise ENES4 discussions.

QUESTIONS FOR DISCUSSION AT ENES 4:

1. Questions related to the 2nd identifier (Market sector information)

1.1 Which market sectors are not addressed by PCs, ACs, or SUs?

Market sectors which are not appropriately addressed by the Use Descriptors should be further identified at ENES 4 and beyond.

1.2 Which elements from NACE, TARIC, UCN would be useful to close gaps in the current use descriptor system?

1.3 Where would well-established sector-specific terminology (crucial for communication) be potentially impaired due to the use of harmonised standard phrases? Provide examples and justification.

1.4 How to deal with exposure scenarios covering 'multiple PC' (or 'multiple SU')?

This is an outstanding question. Several options were considered by the team, as illustrated in the table below, in case one ES covers multiple PCs, bearing in mind the objective of clarity for 'human readers'. More examples could be tested or different options considered at the ENES 4 meeting.

Original title:	Use in formulation of various products (PC 14, 20, 21, 35, 37, 39)
Option 1 - List all PCs:	Formulation; PC14: metal surface treatment products, including galvanic and electroplating products, PC20: products such as pH-regulators, flocculants, precipitants, neutralization agents, PC21: laboratory chemicals, PC35: washing and cleaning products (including solvent based products), PC37: water treatment chemicals, and PC39: cosmetics, personal care products.
Option 2 – 'Multiple PCs' and list codes:	Formulation; (Multiple PCs: 14, 20, 21, 35, 37, 39)
Option 3 - Shorten some PC descriptions:	Formulation; PC14: metal surface treatment, PC20: pH-regulators, flocculants, precipitants, neutralization, PC21: laboratory, PC35:

	washing and cleaning, PC37: water treatment, and PC39: cosmetics, personal care.[1]

1.5 According to which rules is it sensible to combine of PCs and SUs?

Market sectors which are not appropriately addressed by the Use Descriptors should be further identified at ENES 4 and beyond. An action could be defined to do so (See examples 2, 8).

1.6 According to which rules is it sensible to have multiple SUs?

Activities in chemical industry can be indicated with multiple SUs – How to handle this situation (See example 7).

2. Questions related to the 3rd identifier

2.1. According to which rules can different elements considered as '3rd identifier' be combined?

Is it necessary to distinguish them according to their types (technical function, process information, physical form)? What are the consequences of allowing free combinations for harmonisation? (See examples 4, 9).

2.2 Are other additional standard elements needed, based on the experience with currently existing ES?

This should be further analysed and discussed at ENES 4.

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[1] Note: this option would need an update of R12 in the long term, in the meantime, shortened descriptions to be implemented in ESCOM phrases

PROPOSAL FOR HARMONISATION OF EXPOSURE SCENARIO SHORT TITLES

For use in tables of content of SDS annexes

Paper jointly prepared by ECHA – Cefic – DUCC – ESCOM group as input to ENES 4 meeting

2 May 2013

Background

The lack of harmonisation in format and content of exposure scenarios (ES) communicated in the supply chain is widely recognised and has been reported in the recent REACH Review conducted by the European Commission. It is also acknowledged that full harmonisation is not possible in 'one-go' since more experience needs to be gained before standards can be set.

At the ENES 3 meeting in November 2012, the goal of harmonising ES short titles was agreed in principle. At that time, the purpose was to establish a best practice for the table of content (ToC) containing exposure scenario titles at the beginning of the Safety Data Sheet annex. Since the REACH use descriptor (UD) system is well-established, it was proposed to build the ES short titles (and consequently the ToC) from the use descriptors, in an (IT) structured form and based on a set of basic principles (see ENES 3 DUCC presentation and meeting conclusions). Based on the feedback received after ENES 3, it was necessary to refine the proposal and to compare it to some existing ES titles.

In addition, the Cefic team working on ESCOM (Exposure Scenario Communication package: standard phrases and XML schema) advised that ES short titles should be built as much as possible from standard phrases to make these information fields 'transportable' in the supply chain by IT systems.

Against that background, a team composed of representatives from ECHA, DUCC, Cefic and the ESCOM group held several conference calls in order to refine the structure of ES short titles and apply it to 'real-life' exposure scenarios, *i.e.* ES already contained in registration dossiers, reported to M/I by DUs or communicated in the supply chain.

The team agreed that the ES short title is mainly meant to be understood by "human readers" receiving an extended SDS. The short title should help a company (or a sector) to unambiguously and quickly identify which ESs are relevant for their own processes or products. Depending on the substance properties and the circumstances of use, an ES short title may need to be more or less specific, thus some flexibility is needed. At the same time, standard phrases and rules for building the ES titles are needed for enabling translation and IT support, limiting case-specific flexibility.

There was a general agreement that standardised text elements (= standard phrases) would be used in the ES short titles. These should come from the existing REACH use descriptor system, complemented by other standardised text elements where needed. Such complementary elements may exist already or may need to be developed in the ESCom phrase library. Although the use descriptor names may be sometimes difficult to understand for un-experienced or non-trained downstream users, the benefits to base the standardisation as much as possible on the already existing UDs were felt as outweighing this drawback. In addition, increasing REACH experience among all users as well as DU associations' support to DUs should help overcome potential drawbacks in the coming years. Such support can include guidance, examples and training. It may also be an option to refine/shorten some of the use descriptor names (at least when included into the ESCom library) to make them more understandable to readers.

As a result, some 'guiding rules' for building and structuring ES short titles were drafted. A number of examples were used to develop the rules. Further testing of the "guiding rules" with additional examples is needed.

Objective of the exercise

The ES short titles would be used both for the table of content (ToC) relating to the annex of the SDS and the ES short title mentioned in the ES itself. The ToC is meant to assist downstream users in manually sorting out the list of ES and quickly identifying those applying to their sector, thereby reducing their amount of work.

The ToC is also meant to fulfil the requirements related to section 1.2 of the SDS for the substance. In line with the ECHA Guidance on the compilation of safety data sheets[2], section 1.2 of the SDS should remain brief and is meant to focus on the technical function of the substance. It should also be consistent with the identified uses in the CSR and the ES communicated in the extended SDS. This requirement can be fulfilled via a reference to the ToC (see below).

Standardisation in the structure and content of ES short titles will save time to all actors involved in REACH. Once implemented across all sectors, ES received by DUs from different suppliers for the same or for different substances will appear similar. Comparison and further manual (or IT assisted) processing into information for mixtures, and translation of ES titles will be facilitated. Such standardisation will also assist distributors in identifying relevant ES (from multiple suppliers) to be passed on to their customers. Altogether, this will result in in resource efficiencies and, ultimately, in higher compliance level.

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[2] Page 32 of the Guidance on the compilation on safety data sheets

In addition, the proposed approach provides a basis for improving consistency between different REACH documents that require a common understanding of uses, *e.g.* build a clear link between the CSR/exposure assessment information, the ES communicated downstream, and the 'brief general description of uses' in the Technical Dossier.

It is understood that implementing the proposed structure will require some adaptations for M/I (who will have to change their current approach in some cases) and for DU (they will need to be trained to understand the ES short titles and relate them to their own activities). If this is not done now, discrepancies will continue to exist and a large part of the benefits from harmonisation will be lost.

<u>Important notes</u>

1. This work focused solely on ES for substances. It concerns primarily information filed by the M/I or communicated by the M/I to downstream users or distributors. No consideration has been given to SDS of mixtures at this stage.

2. The core assumption remains, like at ENES 3, that the table of content in extended SDS would consist of a list of Exposure Scenarios with their reference (number) and their short title.

3. ES short titles should not be confused with the ES title section (section 1 of ES). The latter can contain more information, such as sector specific applications, process activities, complete list of use descriptors, etc.

4. The chemical industry is vast and diverse, but generally organised in market sectors. Article producers using chemicals are also organised in market sectors or sectors of use. The 'market description' is therefore at the heart of the structure of ES short titles.

<u>Implications</u>

ES short titles are interlinked with similar information elements in other parts of the REACH safety documentation. The REACH legislation requires the following four information elements to be consistent with each other (see Annex I point 5.1.1 and Annex II, section 1.2):

- the *brief general description of use* (as mentioned in Annex VI. 3.5) reported in the Technical Dossier (corresponding to one entry in IUCLID section 3.5, which consists of various description elements; one of these description elements is the "use name")
- the ES *short titles* in the extended SDS
- the sub-headings in chapter 9 of the CSR (name of the exposure scenarios in the CSR)

- the *relevant identified uses* to be included in section 1.2 of the extended SDS (focus on the most common technical functions of the substance and consistency with the attached exposure scenarios)

The most appropriate way to ensure the consistency between the four different information elements mentioned above would be the following:

- 1:1 relationship between uses listed in the Technical Dossier and the exposure scenarios contained in the CSR and in the Safety Data Sheet: each exposure scenario in the CSR and in the extended SDS would correspond to one identified use reported in the Technical Dossier.

- Identity of titles/names: the *names* of the identified uses in section 3.5 of the Technical Dossier, the *short titles* of the exposure scenarios in the Safety Data Sheet and the sub-headings related to the exposure scenarios in the CSR should be the same.

- Cross-reference from section 1.2 of the SDS to the short titles of the exposure scenarios: by including a cross-reference in section 1.2 to the ToC of the ES-annex, the information remaining in section 1.2 is the technical function, since this is not necessarily contained in the ES short title.
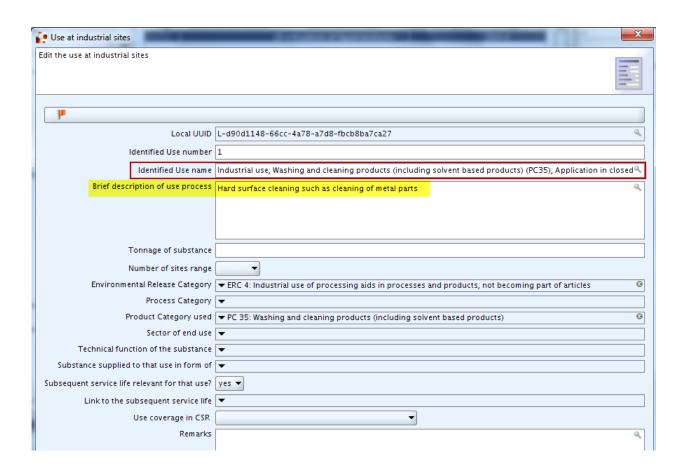
Following such an approach implies that if short titles are built from standard phrases, also the use names in the Technical Dossier would contain standard text elements and no case-specific information. For the time being, the use descriptions in Chesar and IUCLID include (in addition to the use descriptors) a free-text element (the 'use name') where the registrants can express specific aspects of a use/ES as appropriate. The current proposal for the short ES title would imply the recommendation not to use the "use name" field in IUCLID 3.5 for a free-text description on what is done with the substance. As such information may be very relevant in particular for a number of processes carried out by ECHA, such information would need to be included in another IUCLID 3.5 field (to be newly created or to consider whether the current fields "Brief description of use process" or "Further description of article" would be appropriate for that[3]). The phasing of the implementation of such changes in IUCLID will have to be discussed for example in the context of the CSA Roadmap.

Example

Brief general description of use in the Technical Dossier	See **IUCLID screenshot** below. Note that not all fields have been filled as the full example is not known.
ES short titles (extended SDS)	**Industrial use**; *Washing and cleaning products (including*

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[3] It has been noted that for consumer use such field does not exist at the moment and may have to be defined.

	solvent based products) (PC35); <u>*Application in closed systems*</u>
Sub-headings in chapter 9 of the CSR	**Industrial use**; *Washing and cleaning products (including solvent based products) (PC35);* <u>*Application in closed systems*</u>
Relevant identified uses in section 1.2 of the extended SDS	*Solvent, identified uses: see <u>ES Table of Content in this SDS</u>*

PROPOSED GUIDING RULES FOR BUILDING AND STRUCTURING ES SHORT TITLES

The rules proposed below have been developed using examples of existing ES titles. According to the draft rules, the ES short title may consist of up to three elements. These elements are referred to below as 'identifiers'. The 1st and 2nd identifiers are considered as **'mandatory'** in the sense of being expected to be present in the short title for all ES. The 3rd may be added to provide more specificity **if needed**.

<u>Elements of the ES short title:</u>

1st identifier: LIFE CYCLE STAGE, one of the following: formulation / industrial use / professional use / consumer use / article service life (consumer)/article service life (worker)

Notes:

- In order to apply the 'one-of-the-following' guiding rule, SU10 (formulation) prevails over SU3 (industrial use), in the sense that SU3 is not needed if SU10 takes place in at an industrial site, which would be the case in most situations.

- Manufacturing of the substance to which the ES relates is not to be communicated downstream.

- *Industrial use* means "use at industrial sites" and *professional use* means "use by professional workers" (see IUCLID section 3.5). The terms do not refer to the specific meaning of industrial/professional use in the ECETOC Targeted Risk Assessment tool, where these terms imply use conditions leading to a higher or lower level of exposure.

2nd identifier: MARKET SECTOR information: PC name (+PC number) or AC name (+AC code) for ES for service life and/or SU name (+SU number) and/or more detailed standardised qualification of the market sector

The 2nd identifier is meant to provide information on the type of product or article used (PC/AC) and potentially the sector of industry to which the ES is addressed.

It is suggested that the SU name is used if the PC/AC (alone) does not contain the relevant information on which kind of industrial/commercial activity is addressed in the ES (only if more specificity is needed for 'human readers').

For those market sectors which are not appropriately or sufficiently addressed by PC, AC or SU, other descriptors for MARKET SECTOR information can be provided as follows:

- **sub-PC/AC names** (see ECHA guidance on IR/CSA chapter R12)

- **A sub selection of TARIC or UCN codes** (<u>remark</u>: to be included in ESCom catalogue) for further defining the type of product/articles

- **A sub selection of NACE codes** (<u>remark</u>: to be included in ESCom catalogue) for further defining the sector of use.

3rd identifier: Additional information (when relevant)

When other relevant information needs to be included in the short title to specify the content of the ES, this can be done with the 3rd identifier. For certain information types standard phrases already exist, for other cases a selection of standard phrases need to be added to the ESCom catalogue. Such information may relate to

- the technical function of a substance (pick-list as documented in the ECHA guidance on CSR chapter R12)

- Information on the process (e.g. "closed system"; "water-based" or "solvent-based" or "dry" process/product)

- the (physical) form e.g. powdered products or dust forming applications, spray products or aerosol forming conditions.

A series of ES titles used today by M/I or DUs have been assessed against the proposed rules. The exercise deliberately focused on 'relatively difficult cases'. The outcome of this exercise is provided in appendix to this document.

Appendix 1: ILLUSTRATION OF THE GUIDING RULES USING EXAMPLES

	Current ES title:	Use descriptors reported in title section[4]	ES short title proposed **1st identifier**, *2nd identifier*, <u>3rd identifier</u>	Comments / Follow-ups
1	Industrial use as a fuel additive	PC13	**Industrial use;** *Fuels (PC13)*	1st and 2nd identifiers are sufficient for this ES short title. Could consider adding a 3rd identifier in some cases, e.g. if the substance is used specifically in a fuel additive (R12[5] technical function: "fuels and fuel additives")
2	Professional use in film cleaning and copying	PC35	**Professional use;** *Washing and cleaning products (including solvent based products) (PC35); Printing and reproduction of recorded media (SU7);*	2nd identifier: the SU has been used in addition to the PC because it provides useful and complementary information on the industrial activity.
3	Formulation and (re-)packaging of paint removers	PC9a, SU10	**Formulation;** *Coatings, paints, thinners, removers (including solvent based products) (PC9a); removers (paint-, glue-, wall paper-, sealant-remover)*	2nd identifier: Product sub-category ('removers (…)') added as it provides useful information complementing PC9a.
4	Professional use in dry-cleaning	PC35	**Professional use;** *Washing and cleaning products (including solvent based products) (PC35)*<u>; Solvent based</u>; <u>Application in closed systems</u>	Two 3rd identifiers have been used: New standard phrase "Application in closed system" to be created. New standard phrase "Solvent-based" to be created if it does not exist in ESCOM. Similarly, "Water-based" and "Dry process" should be created.
5	Industrial use in surface cleaning (closed systems)	PC35	**Industrial use**; *Washing and cleaning products (including solvent based products) (PC35)*; <u>Application in closed systems</u>	3rd identifier: See above.

[4] Only the following codes are reported here to save space: PC, SU, AC (except SU corresponding to Main User Group)

[5] R12 is used as an acronym for: Chapter R12 of the ECHA Guidance on Information Requirements and Chemical Safety Assessment, *i.e.* the use descriptor system.

	Current ES title:	Use descriptors reported in title section[6]	ES short title proposed 1st identifier, *2nd identifier*, 3rd identifier	Comments / Follow-ups
6	**Industrial use as a bleaching agent for mechanical and recycled pulp**	PC26	**Industrial use;** *Paper and board dyes, finishing and impregnating products; including bleaches and other processing aids (PC26);* Bleaching agents	3rd identifier provides complementary information: the 1st and 2nd identifiers alone do not allow differentiating between two situations corresponding to two separate ES: bleaching agents on one side, and dying activities on the other side.
7	**Industrial use of X1 as catalyst and catalyst precursor**	PC19,20 SU8,9,10	**Industrial use;** *Manufacture of bulk, large scale chemicals (including petroleum products) (SU8); Manufacture of fine chemicals (SU9).* Catalyst and catalyst precursor	2nd identifier: PC19 and 20 are not specific enough to describe the use. Therefore, SU8 and 9 were used for the 2nd identifier. 3rd identifier: Consider new standard phrase: "catalyst and catalyst precursor" (to be created in ESCom catalogue) Note: substance name (X1) not needed in ES short title.
8	**Manufacture of batteries using X1**	PC19, SU16, AC3	**Industrial use;** *Manufacture of accumulators, primary cells and primary batteries*	2nd identifier: PC19 is not appropriate. AC3 is not relevant because this ES does not deal with service life of an article. SU16 ('manufacture of computer, electronic and optical products, electrical equipment') is also too broad. NACE Code 31.4 : 'Manufacture of accumulators, primary cells and primary batteries' is used as 2nd identifier as best descriptor of all options.
9	**Industrial use as solvent in fibre production (including solvent recovery)**	PC32	**Industrial use;** *Manufacture of man-made fibres;* Solvents	2nd identifier: PC32 is not directly relevant. There is no suitable SU. NACE code C20.6.0 – "Manufacture of man-made fibres" was used instead. 3rd identifier: "solvents" (R12: technical function). Solvent recovery is a specific activity that will be found in the main ES.

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[6] Only the following codes are reported here to save space: PC, SU, AC (except SU corresponding to Main User Group)