Developing Generic Exposure Scenarios Under REACH

Guidance supporting the development of Generic Exposure Scenarios as promoted by Cefic as part of the ES development and Communication Model

July 2009, version 0

This is a working document providing guidance on the preparation of Generic Exposure Scenarios for workers, consumers and the environment. Application to the environment is still undergoing active development; relevant elements are highlighted in yellow. The document will continue to be enhanced as experience is gained.

Prepared by:
ESIG (Solvents Manufacturers: Working group on Generic Exposure Scenarios
ESVOC (Solvents Downstream Users): Joint working group with ESIG
CEFIC (Chemical Industry): Project Group on Exposure Scenarios

Foreword

This is a working document providing guidance on the preparation of Generic Exposure Scenarios (GES) for workers, consumers and the environment. Further work is in hand to enhance this guidance and is outlined below.

1. Worker and Consumer

For the Worker and Consumer elements, work is in progress to prepare a supporting package comprising the Microsoft Excel®-based spreadsheet templates described in this guidance as Tables 1 and 2, along with additional explanatory text for their completion. These spreadsheets help consistency and transparency when developing sector specific Generic Exposure Scenarios and have been further developed to aid their use in supporting data transfer within IT systems such as the ECHA CSA Tool (see item 3 below).

2. Environment

Application to the environment is still undergoing active development. Cefic has established a task force to progress the preparation of Specific Environmental Release Categories (SPERCs) as a refinement for the conservative default values supporting the existing Environmental Release Categories (ERCs). Sub-teams are working at the sector level to contribute to this development and to make available SPERCs to map the typical environmental emissions for specific industry sectors to support the CSA process. In addition the project is addressing their role in GES building and taking into account the development of standard phrases for the communication of risk management measures. It is planned to hold a workshop to share learning's and outputs early in the 4th quarter 2009.

3. Templates for Tables 1 and 2 for use mapping and risk characterisation

The information in Tables 1 and 2 in this guidance are being upgraded for use as input for the CSA tool under development by ECHA to support the ease of data transfer. The adjustments to the tables involve minor reorganisation of data in some columns. This is work in progress and will be made available on the Cefic website following review with the ECHA CSA tool project team.

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1. Introduction

This document outlines the process for the development of Generic Exposure Scenarios (GESs) as supported by Cefic as part of their workflow on Exposure Scenario development and supply chain communication (see Appendix 1).
GESs have an important role in supporting the efficient compilation of a library of exposure scenarios for use by Manufacturers/Importers (M/I) and Downstream Users DUs) in compiling their REACH Registration dossiers and in the consistent communication of safe handling information via the eSDS. Their application in the supply chain may be summarized as follows:

DU Associations work with M/Is to develop a library of GESs that are consistent across sectors

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M/Is* identify relevant GESs from library for main Uses

⇩

M/Is* amend/refine the GESs and transform them into substance-specific ES and develop 'tailor made' ESs for niche applications

⇩

M/Is communicate substance-specific ESs and seek feedback in case of gaps in identified Uses

⇩

DUs pass on ESs within supply chain as appropriate. If substance is included in a formulated product, then ES advice for the formulated product is compiled according a recommended approach such as the DPD-plus methodology (available soon).

* Including SIEF/Consortia and their consultants working on behalf of M/I.

1.1. COMPETENCE

The implementation of this process requires input from individuals knowledgeable in the activities involving exposure through the supply chain to the substances undergoing REACH Registration and those competent in human health and environmental risk assessment processes in support of REACH.

2. Background

Part D of The Information Requirements & Chemical Safety Assessment (IR&CSA) Technical Guidance Document (TGD) describes the role that Generic Exposure Scenarios (GESs) have in the efficient communication of information on Risk Management Measures (RMMs) within the supply chain. GESs are recognised as having particular value when they relate to the uses of chemicals (whether as substances or preparations) within a specific sector of downstream industry. Under such circumstances, the GES is able to communicate RMM advice in a manner that addresses the requirements of REACH while aligning with both the technical characteristics of the sector and any jargon that Downstream Users (DUs) in that sector may need to be familiar with.

Although the IR&CSA TGD acknowledges the value of GESs, the benefits have largely been identified as a result of 'testing' the TGD by M/Is and DUs. The benefits can be summarised as delivering:

- A package of relevant RMM information that is targeted to the use of a substance (or group of substances) i.e. it covers, in a single coherent communication, those activities for which a CSA may be required
- Consistency in the GES communications to DUs across different suppliers and substances within a supply chain (and across supply chains when different M/I sectors also choose to work together)
- Standardisation of the language used to describe GESs (and hence the amenability for incorporation into company and commercial IT platforms and structures).

- The likelihood that there will be no unnecessary DU communication arising from the provision of inappropriate ESs into the supply chain, as the process relies on the cooperation of M/Is and DUs at the outset of the process.
- The 'testing' also demonstrated that the GES is unlikely to be able to deliver these benefits unless it is developed in close partnership between M/Is and DUs using a process that is sufficiently comprehensive, transparent and systematic such that all necessary data can be obtained. In this respect:
- They must be developed in a manner consistent with the IR&CSA i.e. the identification and characterisation of RMMs should based on suitable DNELs and PNECs.
- They must be capable of creating an ESs that can form part of the CSR and be contained within the eSDSs.
- They must account for the input from DUs (and DU groups) that are representative for the sector or application that the GES is addressing.
- They should aim to communicate good industry/sector practice as well as align with the requirements of REACH.

Some of the above concepts are not new. For example, the solvents industry (and many other industry sectors) has produced 'safe handling guides' that address the proper use of certain solvents for defined applications. The solvents industry has also worked with DU trade groups to develop a series of good practice guides including a "Guide to Managing Solvent Exposure". Such documents therefore represent a key source of information that has recently undergone critical review and endorsement by key supply chain stakeholders and which, in the context of any initiative to develop GESs for common uses of solvents, should clearly be accounted for.

3. Key definitions

Within this document, the following key definitions are used. A list of acronyms used is to be found in the Glossary in Appendix 7.

Exposure Scenario (ES) this is referred to under REACH as "the set of conditions [usually based around a Process Category (PROC code) for workers, Product Category (PC Code) or Article Category (AC) for consumers or Environmental Release Category (ERC) for the environment] that describe how a substance can be safely used throughout its life cycle, and which include the necessary operational conditions (OCs) and risk management measures (RMMs) which the M/I considers should be implemented to control the risks to human health and the environment associated with the use".
An Exposure Scenario is substance specific.

Generic Exposure Scenario (GES) describes the necessary operational conditions (OCs) and risk management measures (RMMs) which should be implemented to control the risks to human health and the environment associated with the use (or uses) of a group of substances/products with a similar risk profile within a general area of industry (and may extend across several PROCs, PCs/ACs or ERCs). By definition, it aggregates the individual Exposure Scenarios for the various tasks and activities that constitute the general use of the substance/product within a specific sector. It is developed by M/Is in partnership with DU associations.

A Generic Exposure Scenario is applicable for a group of substances with a similar risk profile and aggregates individual Exposure Scenarios for a particular area of application such as a process chemical, cleaning agent or coating.

The title of the GES serves as a mechanism that highlights to a user where a substance may be used and, by implication, how it is likely to be used, but not explicitly for what purpose. The title also represents the means by which the relevant worker, consumer and environmental Operational Conditions (OCs) and Risk Management Measures (RMMs) are communicated within a common ES. A list of indicative GES titles for key chemicals supply chains is contained in Appendix 5.

Although the GES approach is primarily to address groups of substances with similar characteristics, it can also be used to map single substances. In this case, Steps 5 and 6 of the steps to develop a GES are omitted (see Section 4).

Use Descriptor: Part D and Chapter R12 and R16 of the IR&CSA guidance introduce a Use Descriptor System to describe substances uses within the supply chain. This System includes the following components and are referenced in the definitions given above:

Sector of Use (SU): at its broadest level covering industrial workers, public domain (covering professional workers) and private households (covering consumers). IR&CSA Chapter R12.

Product Category (PC) – Type of preparations in which the substance is used (relevant for consumer applications) IR&CSA Chapter R12.

Process Category (PROC) – Type of operations involving potential for worker exposure, IR&CSA Chapter R12.

Article Category (AC) – descriptor for substances in articles with and without intended release. Not addressed within this guidance. Where substances are processed into an article(s) with exposure potential, ACs should be considered alongside PCs for consumer. IR&CSA Chapter R12.

Environmental Release Category (ERC). IR&CSA Chapter R16.

4. Process Outline

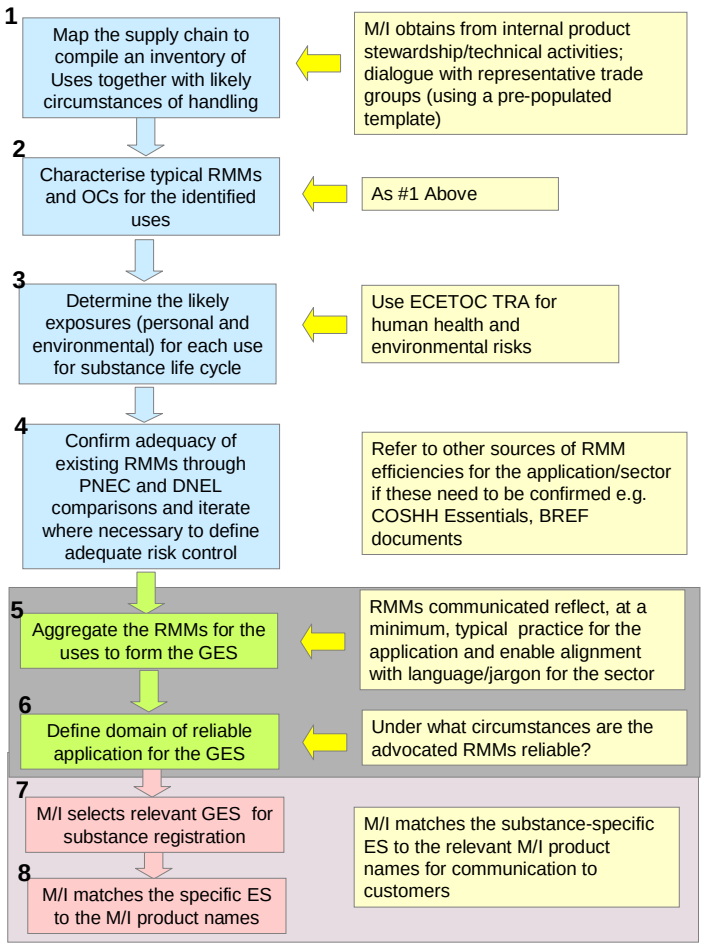
Figure 1 illustrates the main elements recommended for the successful development of Generic Exposure Scenarios and their subsequent translation into a substance-specific ES for inclusion within the substance Registration documentation and extended safety data sheet (eSDS).

The primary responsibility for this implementation process is by Manufacturer/Importers (M/Is) using input from:

- Internal resources, e.g. product stewardship, commercial and technical specialists.
- DU organisations as surrogate for contact with individual customers.
- Dialogue with individual customers (if required).

The process consists of a series of discrete steps that aim to efficiently map the nature of how a substance is used, reduce any uncertainties relating to the use, identify additional information that may help in confirming the integrity of how risks are managed and how these are subsequently communicated in the Exposure Scenario. These steps are expanded in Figure 2 and Section 5.

Figure 1: Key Steps for Developing of Generic Exposure Scenarios



The process draws on the ECETOC TRA Tier 1 modelling tool in the first instance to estimate exposure levels, but allows for the documentation of Tier 2 iterations where these are necessary for demonstration of safe use. The process provides a format for recording of the inputs and outputs from the Chemical Safety Assessment (CSA) and may be used as the basis for supporting the risk assessment reported within the Chemical Safety Report (CSR). In completing the CSR further explanatory text supporting the selection of CSA inputs, their evaluation and associated conclusions is expected to be required.

Figure 2: Core considerations for the development and application of Generic Exposure Scenarios

Step	What	How
I. Map substance applications and characterise exposures through the supply chain – action by M/I organisations with support from DU organisations		
1	For a substance or group of substances with similar applications, M/I maps the supply chain to compile an inventory of Uses involving potential for worker or consumer exposure or environmental release. This is carried out for each defined area of application and forms the basis of the GES. Identify the relevant Sector of Use (Reach Use Descriptor 1) for each life cycle stage, keeping the Sector as general as possible	Compile an inventory of applications for the substance(s) to be registered. For example: process chemicals, cleaning agents, coatings (e.g. paints/decorative coatings, inks, adhesives), lubricating agents (e.g. lubricants, greases). In addition general activities such as manufacture, storage and distribution, formulation and packing should be identified. For each application, opportunities for exposure are identified covering each lifecycle stage of the supply chain. Identify relevant Downstream User Associations to assist with verifying the mapping exercise
2	For each area of application, determine the contributing scenarios and those Operating Conditions (OCs) and Risk Management Measures (RMMs) that are currently used to control worker/consumer exposures and environmental releases. Map each Use involving potential for exposure to the relevant REACH Use Descriptor: Worker – Process Categories (PROC) Consumer – Product Categories (PC)/Article Categories (AC) Environment – Environmental Release Categories (ERC) or equivalent Review with relevant DU Organisation.	Use Table 1 of the standardized mapping Microsoft Excel®-based spreadsheet format template. Separate templates are available for worker, consumer and environment. Review the outcome of the mapping exercise with representative DU Organisations for accuracy and completeness and adjust as needed. This may be done at this point, or for efficiency, combined with the DU review carried out as part of later steps. See examples given in Section 5.1.

II. Evaluate risk and document the Chemical Safety Assessment – action by M/I organizations with support from DU organisations		
3	Carry out exposure estimates for workers, consumers and/or the environment for each identified Use included within the mapping exercise. Consider relevant routes of human exposure (inhalation, skin, oral) or environmental emission (air, water, land/sediment).	Estimate/predict exposures using available Tier 1 modelling tools, e.g. ECETOC TRA. Identify OCs/RMMs applied to modify the Tier 1 estimates Document results using Table 2 of the standardized Microsoft Excel®-based spreadsheet format template for worker, consumer or environment. Divide analysis according to relevant health and environmental ranges, e.g. volatility or dustiness, log KOW
4	Confirm adequacy of the existing typical RMMs taking account of appropriate RMM efficiencies through comparison with actual or representative DNELs and PNECs. Iterate where necessary to define adequate risk control and demonstrate safe use. List the RMMs for each Use as standard phrases to support compilation of the required risk control measures for communication to Downstream Users using meaningful language. These may include recommended measures in support of product stewardship in addition to those required for demonstration of safe use under REACH. Review with relevant DU Org. Reality check that recommended RMMs are appropriate and practical. Where identified RMMs/OCs are not in line with existing practice work with DU Org to obtain further Tier 2 information	Compare the exposure estimates for the relevant volatility or dustiness ranges with relevant DNELs and/or PNECs. For the development of the GES it is only necessary to have available a DNEL or PNEC representative of a substanceFootnote. Prior to final registration a verification step with the actual DNEL/PNEC is required. Safe use is demonstrated if the result is below unity. If safe use cannot be demonstrated carry out Tier 2 iteration to verify actual risk reduction is greater than the Tier 1 default for a particular RMM or identify additional RMMs. Document results in Table 2 in support of the Chemical Safety Assessment Draw on the RMM standard phrase library being prepared as part of the GES process to compile the relevant list of RMMs for communication purposes. Identify additional phrases if needed.

Footnote to point 4: For certain groups of substances having similar hazardous properties it may be possible to use a DNEL/PNEC for the whole group. This requires expert judgment.

III. Compile the GES and include within the industry or Sector GES library(ies) – action by M/I organizations with support from DU organisations		
5	Compile the GES for the area of application (divided by industrial, professional or consumer as required) using the REACH ES Template format Review with DU and incorporate refinements as appropriate	Aggregate the list of Uses (contributing scenarios) and associated RMM phrases. Include RMM phrases required for the demonstration of safe use Consider inclusion of additional RMM phrases in support of product stewardship recommendations
6	Define the domain of reliable application for the GES Make GES available for inclusion within the industry GES library for access by relevant stakeholders DUs may choose to develop a complementary GES to incorporate standard Sector-specific terminology	The domain of reliable application is defined by the list of Operating Conditions and substance characteristics against which the RMMs are relevant, e.g. relevant DNEL/PNEC range, volatility, exposure duration, emission volume, operating temperature
IV. Convert the GES into a substance-specific ES for registration and customer communication – action by Registrant with input from customers if required		
7	M/I selects the relevant GES to form the basis of their substance-specific registration M/I amends the GES and supporting CSA documentation as required and incorporates within their Chemical Safety Report	M/I confirms suitability of the GES by reference to substance-specific criteria e.g. DNEL/PNEC values, volatility, dustiness. GES is refined as necessary to form the substance-specific ES
8	M/I matches the substance-specific ES to the relevant M/I product names for communication to customers M/I makes available the product ES for review by customers pending finalization and inclusion within e-SDS.	M/I is advised to follow the supply chain communication model recommended by Cefic, FECC and DUCC in seeking feedback from their Downstream Users The use of coded standard phrases in the development of the GES allows for the ready translation into company-specific Safety Data Sheet systems.

Footnote to Step 8: For multi-component products, it is recommended to develop the product ES in line with the DPD-Plus methodology[1]

[1]DPD-Plus methodology – Guidance for the development of Exposure Scenarios for formulations based on selecting the ES for the component substance(s) which drive the hazard classification according to the Dangerous Preparations Directive (DPD).
Available on the Cefic website: http://cefic.org/templates/shwPublications.asp?HID=750

5. Development of Generic Exposure Scenarios (GESs)

Following discussions between M/Is and DU associations aimed at delivering the efficient and reliable development of any GES, an Microsoft Excel®-based spreadsheet format has been developed that aims to facilitate:

- An agreed characterisation of the uses of the of relevant group of substances (e.g. low volatility liquids) within the supply chain (or defined parts of it)
- The systematic collection, confirmation and processing of relevant information in the development of the GES
- The initial creation of the GES by the M/I and, where necessary, it's subsequent refinement following feedback by DUs
- Standardisation of how the GES is structured and described both in order to ensure that the GESs that DUs receive are similar from different M/Is and to facilitate the efficient integration of GESs (and associated substance-specific ESs) into the IT systems of M/Is e.g. for the creation of SDSs.

5.1. Mapping Information on Application and Uses (GES Process Steps 1 and 2)

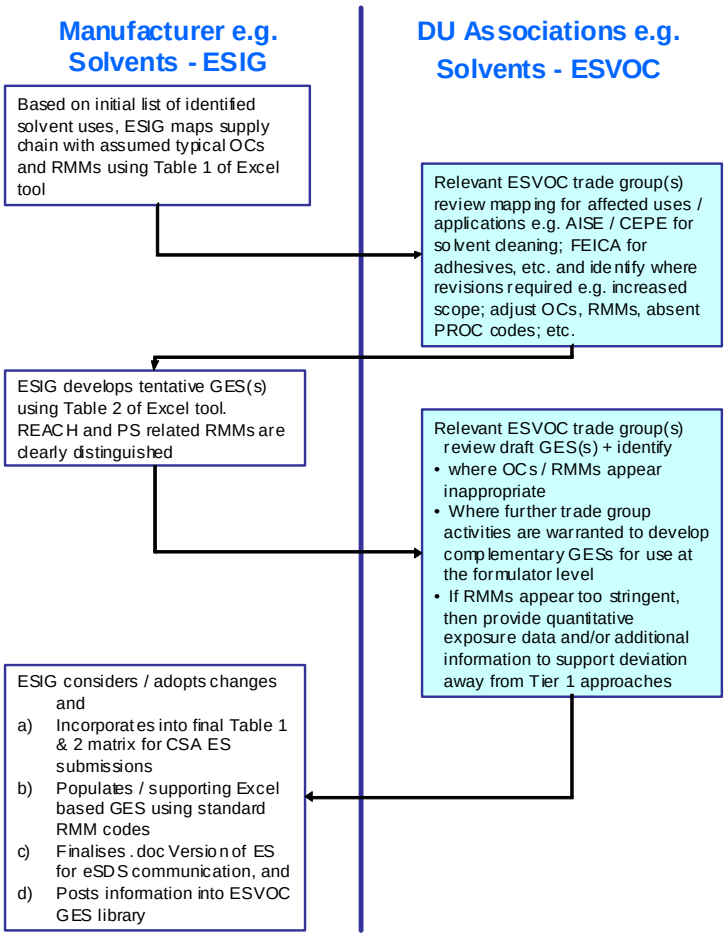
Part D of the IR&CSA TGD provides guidance on how M/Is may obtain information from within their own organisations and via the supply chain that describes the uses of a substance. Although the TGD contains basic flow charts, DUCC/FECC/Cefic have now developed a detailed process (Appendix 1) that offers advice on how this may be efficiently accomplished. In order to develop GESs, it is foreseen that a M/I needs to:

- Understand in which sectors of industry his substance is likely to be used, but not necessarily what it may be used for, and
- Have a knowledge of, or be able to make reasonable assumptions on, the likely exposure controls (both as Risk Management Measures and operational conditions) that are likely to affect exposures/emissions to man and/or the environment

Much of this information is already likely to reside within M/I organisations as a result of marketing, technical support and product stewardship related activities. So in many instances organisations will possess sufficient information to start the process of developing ESs. However, because the GES process is a partnership between the M/I and DU, then before the M/I begins to undertake the CSA, there is a need to confirm with the DU that the knowledge/assumptions are in-line with the understandings of the DU group(s) for which a GES may be applicable. For this reason, the process of GES development foresees a continued dialogue between the M/I (or M/I groups and associations) and their DU equivalents (as representatives of the wider DU community) in order to both confirm and/or refine the GES and its supporting data. This is outlined in Figure 3, where the M/I group is ESIG, the European solvent manufacturers, and a coalition of DU groups is represented by ESVOC.

Where DU-authored GESs are available for identified uses, these should serve as a key input to this mapping process.

Figure 3: The Involvement of M/Is and DUs in the Creation of GESs



To facilitate the efficient compilation and communication of the information required to develop any GES (or ES), the solvents sector (via ESIG and ESVOC) have developed a Microsoft Excel®-based spreadsheet format that systematically documents and verifies the key information required at the Tier 1 level, in-line with the process shown in Figures 1 and 2. The format allows the M/I to fully and transparently map their initial understandings of the substance (groups of substances) applications and associated uses throughout the life cycle and to then work with appropriate DU organisations (in lieu of specific contacts with DUs themselves) to make any adjustments before undertaking the initial CSA for the uses. Because of the nature of the information required to characterise environmental and human emissions differs, then the format respects this and allows the information to be collated in manner that still enables the communication of an integrated (human and environmental) GES. The information contained in Table 1 of the format is shown in Figures 4a, 4b and 4c below.

5.1.1. MAPPING OF WORKER APPLICATIONS AND USES

The process for mapping worker exposures for the use cycle is undertaken using Table 1 of the Microsoft Excel®-based spreadsheet format shown in Figure 4a. The life cycle is first broken down into common areas of application for the relevant group of substances, refer to Appendix 5 for an example list of application areas a number of which may comprise the life cycle for a particular substance. For each application opportunities for exposure are identified covering each lifecycle stage and described in the common terms for the sector and represented as 'contributing scenarios'. The example shown in Figure 4a illustrates the mapping associated with the industrial use of coatings. .
The common descriptions are then 'transformed' into a form that is consistent with the expectations of the IR&CSA TGD i.e. Use Descriptors (in this case Process Categories for workers) are applied and relevant typical RMMs and OCs noted. This use mapping is continued for all identified applications and for different substance types e.g. in the case of solvents, the RMMs and OCs often differ markedly when low and high volatility solvents are used and hence these differences need to be recorded.

Figure 4a: Example GES Format of Table 1 Worker: Mapping uses and associated use conditions for workers – application of coatings in an industrial setting

Table 1: Mapping Uses in the Supply Chain					
					Use Descriptor
	User Group	Contributing Scenarios	Typical Mapped Operating Conditions	Typical Mapped RMMs	Process Category / TRA equivalent
Coatings (industrial)	Industrial - SU3	Bulk transfers	Daily; 15 min - 1 hour; ambient temp; collection of line waste in container	Enclosed transfers, vented transfer points; clear lines prior to decoupling	PROC8b Dedicated discharging to/from vessels
	Industrial - SU3	General process exposures from enclosed processes	Continuous; daily; 8hour	Enclosed process; closed/semi-closed sampling point	PROC1 and PROC2 / TRA2 Closed continuous process
	Industrial - SU3	General process exposures from closed processes	Batch process; daily; ambient temp.	Closed equipment, enclosed or vented transfer points	PROC 3 and PROC4 / TRA4 Closed batch process
	Industrial - SU3	Charge from drums	Daily; 15 mins - 1 hour; ambient temp	Pumped transfer from drum to holding tanks.	PROC8b / TRA7 Discharging to/from vessels
	Industrial - SU3	Printing	Daily; >4 hours, ambient	Local exhaust ventilation at rollers; remove spills as they occur, PPE	PROC10 / TRA9 Roller application and brushing
	Industrial - SU3	Roller and equipment cleaning	Daily; 15 min - 1 hour; ambient temp;	collection of waste and wipe cloths in container. PPE.	PROC13/ TRA11 Uses by dipping/pouring

Footnote to Figure 4a: GES process Table 1 describes the mapping of the industrial application of coatings for workers. The RMMs listed are additional to the assumption that a basic standard of occupational hygiene is implemented, e.g. covering the regular supply and laundering of work clothing, provision of washing and changing facilities, eating and smoking is undertaken in areas separate from the workplace, provision of general ventilation to the workplace.

5.1.2. MAPPING OF CONSUMER APPLICATIONS AND USES

Figure 4b illustrates the Table 1 mapping template for the consumer uses of coatings. In a similar manner to that applied for workers, its basis lies in characterizing the range of likely uses in terms of the relevant Use Descriptors, in this case the Product Category (PC) for consumers. However, because the Product Category can be a fairly coarse indicator of how a substance can be encountered in different consumer settings, it may be necessary to introduce a further level of refinement. This is achieved by the use of the ECETOC TRA product sub-categories that link to each PC examples of which are shown for adhesives (PC1) and coatings (PC9) in Figure 4b. Refer to the ECETOC TRA for details of the sub-categories.

Figure 4b: Example GES Format of Table 1 for Consumer: Mapping consumer uses of coatings

Table 1: Mapping Consumer Uses in the Supply Chain				
Relevant Product Categories	Product sub Category Sentinels	TRA Product Ingredient (dermal/oral/inhalation) (g/g) .. Red where default differs to TRA	TRA Default Skin Surface Area / Amount Swallowed (g) / Amount Used (g) .. Red where default differs to TRA	Adult / Child
Consumer Uses of Coatings				
PC1:Adhesives, sealants	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	0.3 / Nr / 0.3	858 / Nr / 15000 (1000)	A
	Glues, hobby use	0.3 / Nr / 0.3	36 / Nr / 9	A
PC4:Anti-freeze and de-icing products	Removers (paint-, glue-, wall paper-, sealant-remover)	0.9 / Nr / 0.9	858 / Nr / 2000 (500)	A
PC5: Artists supply and hobby preparations	Finger paint, face paint	0.5 / 0.5 / Nr	254 / 1.35 / Nr	C
PC9:Coatings and paints, fillers, putties, thinners	solvent rich, high solid, water borne paint	100% 0.3	858 / Nr / 1300 (500)	A
	waterborne latex wall paint	0.5 / Nr / 0.5 (0.05)	429 / Nr / 3750 (2000)	A
PC10:Building and construction preparations not covered elsewhere	Removers (paint-, glue-, wall paper-, sealant-remover)	100% 0.3	858 / Nr / 2000	A
PC24:Lubricants, greases, and release products	Liquids	0.5 / Nr / 0.5	858 / Nr / 5000 (100)	A

Footnote to Figure 4b: The consumer mapping characterises the default assumptions used to predict exposures. These defaults are contained in version2 of the ECETOC TRA and are iterable. Therefore the mapping includes both the pre-set values and those that are considered most representative of the use to apply to determine the predicted exposures. To help differentiate between the values for Oral, Dermal and Inhalation these have been

highlighted using different colours, black, blue and green respectively. Where the default values given in the TRA have been adjusted these are highlighted in red.

5.1.3. MAPPING ENVIRONMENTAL EMISSIONS

For each of the consumer and worker uses mapped so far, the associated environmental emissions also have to be mapped. Using the worker and consumer examples, Figure 4c is compiled to represent the environmental emissions mapping. The emissions mapping involves assigning an application or use with the corresponding Environmental Release Class (ERC). However, as the ERCs can be rather coarse indicators of how much of a substance is emitted to the environment as a result of a particular use, it is usually necessary to introduce a further level of refinement. This is achieved by using an appropriate specific ERC (SpERC). Note, because each SpERC requires a justification for its basis (in terms of which exposure determinants differ from those in the related ERC), these are still under development. It should also be noted that the parameters used for the SpERCs remain indicative until they are justified and confirmed.

Mapping uses to ERCs and SpERCs defines first of all whether uses are industrial (i.e. defined point sources) or wide dispersive (i.e. consumer or professional uses which result in continuous emissions that are more or less evenly distributed in a geographic area). In addition, the assignment of SpERCs goes along with assigning exposure modelling parameter such as the number of emission days, whether or not waste water is treated in a sewage treatment plant, waste handling, and risk management ' wide dispersive' use is of significance for risk communication. The combined total of wide dispersive uses results in overall wide dispersive emissions. These are not subject to specific emission reduction measures. For that reason, all wide dispersive uses are assessed together.

In contrast, industrial uses occur at defined sites with defined operational conditions. The respective exposure scenarios specify the operational conditions and, if required, the risk management measures that need to be in place to deliver the appropriate level of risk control i.e. circumstances that when taken together result in a PEC/PNEC ratio of <1.

The development of SPERCs and their role in GES building remains an activity still under development. The format and rationale for SPERCs as illustrated in figures 4C and 5C, included as illustrations of how the concepts may be realised. Cefic intends providing supplementary advice in this area (currently under development).

Figure 4c: Example GES Format of Table 1 for Environment

Use		SU	ERC	ERC Description	Typical mapped Operating Condition	Typical mapped RMM ERC	SPERC	Emissions fractions to Air	Water	Soil
Consumer Use of Coatings	PC1 adhesive and sealants	21	8c,f	Wide dispersive indoor /outdoor use resulting in inclusion into or onto a matrix	Frequency of use: 365d/y; STP: yes	none	Allow residues to dry/cure, dispose of residues as solid waste	ERC: 15% (all) SPERC: 100% (solvent), 0% other	ERC: 1% (all) SPERC: 0% (solvent), 1% other	ERC8c: 0% ERC8f: 0.5% SPERC: 0%
	PC4 Anti-freeze and de-icing products	21	8d	Wide dispersive outdoor use of processing aids in open systems	Frequency of use: 365d/y; STP: yes	none				
	PC5 Artists supply and hobby preparations	21	8c	Wide dispersive indoor use resulting in inclusion into or onto a matrix	Frequency of use: 365d/y; STP: yes	none	Allow residues to dry/cure, dispose of residues as solid waste	ERC: 15% (all) SPERC: 100% (solvent), 0% other	ERC: 1% (all) SPERC: 0% (solvent), 1% other	ERC8c: 0% SPERC: 0%
	PC9 Coatings and paints, putties and fillers	21	8c,f	Wide dispersive indoor /outdoor use resulting in inclusion into or onto a matrix	Frequency of use: 365d/y; STP: yes	none	Allow residues to dry/cure, dispose of residues as solid waste	ERC: 15% (all) SPERC: 100% (solvent), 0% other	ERC: 1% (all) SPERC: 0% (solvent), 1% other	ERC8c: 0% ERC8f: 0.5% SPERC: 0%
	PC10 Building and construction preparations not covered elsewhere	21	8c,f	Wide dispersive indoor /outdoor use resulting in inclusion into or onto a matrix	Frequency of use: 365d/y; STP: yes	none	Allow residues to dry/cure, dispose of residues as solid waste	ERC: 15% (all) SPERC: 100% (solvent), 0% other	ERC: 1% (all) SPERC: 0% (solvent), 1% other	ERC8c: 0% ERC8f: 0.5% SPERC: 0%
	PC24 Lubricants, greases, and release products	21	8c	Wide dispersive outdoor use of substances in closed systems	Frequency of use: 365d/y; STP: yes	none				
Industrial Coating	Industrial coating	3	5	Industrial use resulting in inclusion into or onto a matrix / solvent-borne coatings	Frequency of use: 250d/y; STP: yes	none	Enclosed transfers and processes, collection of waste.	ERC: 50% (all) SPERC: 100% (solvent), 0% other	ERC: 50% (all) SPERC: 0% (solvent), 1% other	ERC5: 0% SPERC: 0%

5.1.4. General Characteristics of GES Table 1 use mapping

The form and contents of Table 1 in Figures 4a-4c demonstrates the following characteristics, namely they:

- identify the characteristics of any use i.e. whether it is discrete or, more usually, consists of a series of component activities (or PROCs or PCs), together with the RMMs and OCs that are expected to be associated with each (i.e. the starting point is a determination of whether the 'current controls' are sufficient to ensure risks are managed effectively.
- allow the users to focus on the nature of the key risk management measures (in terms of how these are addressed within the TGD screening models e.g. the ECETOC TRA), and those OCs that are likely to be typically encountered in each setting.
- adopt a common terminology for cataloguing and describing the uses (both as a GES title together with a title for each 'contributing scenario') which, in turn, is then used as the basis for a common (and consistent) approach to how the RMMs are subsequently communicated within the GES.
- describe the nature of the OCs and RMMs that are typically encountered. The starting point for the GES is therefore an assessment of whether the current conditions are acceptable under REACH i.e. assuming they are, then DUs receive an ES that confirms that the 'business as usual' case has been determined to be safe by the M/I.
- represent a sound and reliable process by which a M/I can 'map' the uses of a substance (or group of similar substances) against the relevant Use Descriptors (and which form part of the mechanism for Registration and DU communication).

The information, at this point, does not describe whether the risks are controlled or not. It is more of an 'inventory' of existing knowledge and practice that the M/ I can refer to when developing the GESs for the uses of the substance. However it also allows a M/I to identify where different sectors of industry may use the substance in similar ways. For example, they might indicate that a similar pattern of use occurs in both the manufacture of substance and its application as a chemical feedstock, which would then indicate the possibilities that the mapping may be interchangeable and that one common ES may only be required to cover the uses for both identified applications, subject to confirmation in the CSA.

5.2. Confirming the Mapped Data (GES Process Step 2)

The Table 1 Use mapping prepared by the M/I is then used as the basis of a discussion with the appropriate DU association(s) to confirm that the M/I's understandings are correct. This is then confirmed or further refined to ensure that the narrative descriptions align as much as possible with the technical language/jargon that may be used within a sector/area of use.

This is relevant for all but particularly relevant in the case of exposure scenarios for consumer applications, where the default values for the Product Categories that are contained in version2 of the ECETOC TRA are conservative and represent the upper boundaries of use. It is therefore appropriate to verify with DUs that these values are relevant for the circumstances in which any substance, or group of substances, may be used, and to provide an appropriate justification of alternative values where these are considered more appropriate. Table 1 continues to be used as the basis for discussion and recording this information.

Experience indicates that this initial dialogue is most constructively undertaken as a face-to-face discussion. If a good understanding of DU applications is known by the M/I, it is also possible to combine this verification of use information with Step 5.

5.3. Processing ES Information (GES Process Steps 3 and 4)

Following the receipt of feedback from the DU, the next step is for the M/I to determine the adequacy (or not) of the prevailing RMMs and OCs. While the information in Table 1 characterises the commonly encountered RMMs and OCs, there is a need to verify that they are adequate to manage the risks. This step requires that a comparison with the DNEL and/or PNEC is carried out for the relevant tasks/activities which may be iterated as appropriate to support the demonstration of safe use and support the Chemical Safety Assessment (CSA.

Table 2 of the GES Microsoft Excel®-based spreadsheet format allows the information contained in Table 1 to be further developed to identify those areas of use (or tasks) where the risks may be unacceptable and where further RMMs may be appropriate and/or further dialogue is appropriate with the DU. For example, to determine whether key assumptions remain valid or to collect further information which would allow for iteration of assumptions.

Both the workplace and consumer exposures associated with different situations where human exposure may occur are calculated using version2 of the ECETOC TRA model. Environmental exposures are predicted using EUSES (using either the relevant ERC for the use scenario or default parameters [from Tables A and B] that are valid for that situation) and where a summary of their scientific basis is described in Appendix 5. However, while the process uses a Tier 1 tool (the ECETOC TRA) to help guide discussions, the level of detail and iteration is more a reflection of a Tier 2 process than a simple risk screen i.e. the GES development process is resource intensive and requires access to knowledgeable expertise.

The adequacy of the identified RMMs and OCs is evaluated by comparing the TRA/EUSES exposure predictions for the target population with DNELs or PNECs that are considered indicative of such categories. A similar process can be applied for a specific substance. In this case the predicted exposures can then be compared to the relevant DNEL or PNEC for the material.

As the Table 1 mapping has been developed based upon prevailing industry practice, it is anticipated that the majority of controls in place may be judged acceptable by REACH, as current practice will reflect the combination of prevailing regulatory requirements together with the accumulated industry experience of successfully managing risks for that use. But this will not always be the case. In those cases where the controls are deemed insufficient, then there will be a need for the M/I to engage in a further round of dialogue with the DU either to:

- identify additional and/or more stringent exposure controls such that the risks associated with the use can be deemed to be acceptable under REACH, or
- acquire more information (such as on the levels of exposure or efficiencies of control associated with the use of the substance) to demonstrate that actual exposures are less than DNELs or PNECs

The Excel spreadsheet format incorporates different mapping templates dependent on the identified exposed population (workers and consumers) and the nature of the emissions (human health or the environment). Although it would be desirable to have a common template for this task, because of the need to collect widely different information on the exposure determinants that serve the respective exposure models (ECETOC TRA or EUSES), then it is more effective to use different templates. Figure 5a shows how Table 2 is used to collect and process information to derive exposure predictions to workers (using the example of the industrial use of coatings first described in Figure 4a), and Figures 5b and 5c contain Table 2 for the situations represented in Figures and 4c for Consumer and Environment respectively.

Figure 5a : GES Format of Table 2: Characterising the Risks (Industrial Use of Coatings) – Worker

	Table 1: Mapping Uses in the S		Table 2: Characterising the Risk - Low VP Liquids - Chemical Safety Assessment - Evaluation of Safe Use						
			Tier 1 assumptions and adjustments where required		Predicted Exposure - ECETOC TRA estimate				
	User Group	Contributing Scenarios	OCs (red text Tier 1 adjustments)	RMMs (red text additional Tier 1 adjustments)	Low Volatility (ppm) no LEV	LEV Efficiency (XX if not TRA)	Predicted Exposure (ppm)	Relvant Exposure modifiers	Predicted Dermal (mg/kg/d)
Coatings (industrial)	Industrial - SU3	Bulk transfers	daily; ambient temp.	With LEV	5	97	0.15		0.07
	Industrial - SU3	General process exposures from enclosed processes	>4 hours, ambient temp.	With LEV	1	90	0.1		0.14
	Industrial - SU3	General process exposures from closed processes	>4 hours, ambient temp.	With LEV	5	90	0.5		0.69
	Industrial - SU3	Charge from drums	daily; ambient temp.	No LEV	5	90	0.5	Use of drum pumps considered to offer 90% exposure reduction	3.43
	Industrial - SU3	Printing	> 4 hours; daily; ambient temp.	With LEV.	10	90	1		1.37
	Industrial - SU3	Roller and equipment cleaning	daily; ambient temp.	With LEV.	10	90	1		13.71

Footnote to Figure 5a: Table 2 illustrates how the exposure predictions are made using the mapped information and using version2 of the ECETOC TRA tool. This tool allows adjustment for exposure duration, substance concentration and whether or not respiratory protection is used. The mapping is based on the standard defaults (8 hour exposure, 100% concentration and no RPE) unless specifically identified (in the column marked 'exposure modifiers'). Dermal exposures are predicted for each contributing scenario/PROC in addition to the inhalation exposure. In-line with the IR&CSA TGD recommendations, oral exposures are not considered significant for worker exposures.

Version2 of the TRA includes pre-set defaults for the ventilation efficiency considered representative for any PROC. Where, as a result of the DU dialogue, these values are considered inappropriate, then provision exists to also note (and account for) such information when predicting exposures. These steps illustrate the fact that the GES process involves both Tier 1 and Tier 2 considerations. The Tier 1 element (the ECETOC TRA) represents an efficient means to direct discussion and resource. However, the manner and level at which OCs and RMMs need to be described to adequately demonstrate the control of risks frequently necessitates the inclusion of Tier 2 elements.

Figure 5b : GES Format of Table 2: Characterising the Risks (Consumer Use of Coatings)

Table 1: Mapping Co		Table 2: Characterising the Risk						Indicative DNEL 10 mg/kg/d	Indicative DNEL 50 mg/kg/d
Relevant Product Categories	Product sub Category Sentinels	Relvant Exposure modifiers	Comments	Substance Specific RCR (dermal)	Substance Specific RCR (oral)	Substance Specific RCR (inhalation)	Substance Specific RCR (all routes)	RMMs for communication - Consolidate into GES or e-SDS (Black text REACH advised; Blue text recommended)	RMMs for communication - Consolidate into GES or e-SDS (Black text REACH advised; Blue text recommended)
Consumer Uses of Coatings									
PC1:Adhesives, sealants	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	Use in a well ventilated space (0.1x). Equivalent to 3-5 acph	15Kg daily use of 30% most unlikely. 3 hrs use relevant for 1Kg	0.02	0	1.35	**1.37**	Open doors and windows to provide natural ventilation. Wash any residues off skin after use. Do not use more than 750g on any day.	Open doors and windows to provide natural ventilation. Wash any residues off skin after use. Do not use more than 3.75Kg on any day.
	Glues, hobby use			0.00	0	0.12	**0.12**	No RMMs identified.	No RMMs identified.
PC4:Anti-freeze and de-icing products	Removers (paint-, glue-, wall paper-, sealant-remover)	5% dermal absorption most relevant for HCSs	2Kg daily consumer use of 90% most unlikely. 500g assumed	0.06	0	2.7	**2.76**	Open doors and windows to provide natural ventilation. Wash any residues off skin after use. If using for more than 2 hours then use RPE	Open doors and windows to provide natural ventilation. Wash any residues off skin after use.
PC5: Artists supply and hobby preparations	Finger paint, face paint			0.06	0.068	0.00	**0.13**	No RMMs identified.	No RMMs identified.
PC9:Coatings and paints, fillers, putties, thinners	solvent rich, high solid, water borne paint	100% not realistic for HCSs. 30% assumed.	1.3Kg daily consumer use of 100% most unlikely. 0.5Kg assumed	0.07	0	0.495	**0.57**	Use in a well ventilated area. Wash any residues off skin after use. Where more than 100g used, then open doors and windows to provide additional ventilation	No RMMs identified.
	waterborne latex wall paint	50% not realistic for HCSs. 5% assumed.	3.75Kg daily consumer use most unlikely. 2Kg assumed	0.01	0	0.24	**0.24**	Use in a well ventilated area. Wash any residues off skin after use. Where more than 1000g used, then open doors and windows to provide additional ventilation	No RMMs identified.

Footnote to Figure 5b: Table 2 illustrates how the exposure predictions are made using the mapped information and using version2 of the ECETOC TRA tool. This tool allows adjustment for various defaults dependent on what are considered the relevant routes of exposure (and which are defined by the PC). These include substance concentration, quantity in use and likely exposure area. The mapping is based on the standard defaults unless specifically identified (and marked in red in the columns marked 'exposure modifiers' and 'comments. In-line with the IR&CSA TGD recommendations, oral exposures are not considered significant for worker exposures.
Version2 of the TRA includes pre-set defaults for the exposure duration considered representative for any PC. Where, as a result of the DU dialogue, these values are considered inappropriate, then provision also exists to note/justify (and account for) such information when predicting consumer exposures. Similarly, the IR&CSA TGD takes no account of the effectiveness of identified consumer RMMs such as the impact on exposure of product design or enhancing the effectiveness of ventilation through opening doors and windows. Again, provision exists within Table 2 to note/justify (and account for) such information.
The OC's and RMM's identified within the ES (two right hand columns of figure 5b) represent the outcome of the application of the ECETOC TRA and are intended to help focus discussion between the M/I and DU on where further (Tier 2) refinement may be required in order that the final ES ensures safe use by consumers.

Figure 5c: GES Format of Table 2: Characterising the Risks (Emissions to the Environment)
Example – Placeholder - to be confirmed

GES Title / Area of Use	Typical OC	Typical RMMs	Typical OCs (Local)	Typical RMMs (Local)	Predicted exposure concentration (EUSES output)			Confirmed RMMs	Substance Characteristics
					Air	Water	Sediment		
Extraction agent	Volume 600 Mt per year 225 emmision days per year. Fraction of main local source = 1 Dilution factor (freshwater) = 10x	Recovery of solvent from waste water via stripping Treatment of waste water at Municipal sewage treatment works	Volume 1180 Mt per year 225 emmision days per year Fraction of main local source = 0.776 Dilution factor (freshwater) = 10x	Recovery of solvent from waste water via stripping (99% efficiency) Treatment of waste water at municipal swerage treatment works	0.33 mg/m3	4.6 x 10-4 mg/l	1.63 x 10-2 mg/kgw/wt	Recovery of solvent from waste water via stripping. Treatment of waste water at municipal treatment plant	Readily biodegradable PNEC 0.002 mg/l Volatility <100 hPa

Footnote to Figure 5c:
Based on the use of EUSES calculated using the ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) EUSES spreadsheet tool and an assumed PNEC of xxx mg/kg/d (applicable across all exposure routes).

5.4 Determination of Required RMMs (Process Step 4)

Figures 4 and 5 illustrate how the uses of a substance are mapped and subsequently processed in order to predict the relevant exposures associated with any use. Figures 6a and 6b illustrate how this information is then taken forward to identify appropriate RMM phrases to support safe use and which form the basis of the narrative-based GES for communication purposes, further explained in Section 5.5.

Figure 6a: Determination of Required RMMs in GES development (worker)

	Table 1: Mapping Uses in the		Table 2: Characterising the Risk				DNEL 10
	User Group	Contributing Scenarios	te Predicted Dermal (mg/kg/d)	Substance Specific RCR (inhalation)	Substance Specific RCR (dermal)	Substance Specific RCR (all routes)	RMMs for communication - Consolidate into GES or e-SDS (Black text REACH advised; Blue text recommended)
Coatings (industrial)	Industrial - SU3	Bulk transfers	0.07	0.015	0.014	0.029	Ensure transfer points are supplied with extract ventilation. Clear lines prior to decoupling.
	Industrial - SU3	General process exposures from enclosed processes	0.14	0.01	0.028	0.038	Handle substance within a closed system. Ensure material transfers are under containment or extract ventilation.
	Industrial - SU3	General process exposures from closed processes	0.69	0.05	0.138	0.188	Handle substance within a closed system. Ensure material transfers are under containment or extract ventilation.
	Industrial - SU3	Charge from drums	3.43	0.05	0.686	0.736	Use drum pumps in well-ventilated area. Wear suitable gloves (type EN374). Avoid spillage when withdrawing pump.
	Industrial - SU3	Printing	1.37	0.1	0.274	0.374	Handle substance within a contained system. Provide extract ventilation to points where emissions occur.
	Industrial - SU3	Roller and equipment cleaning	13.71	0.1	2.742	2.842	Undertake in-place equipment clean-downs by pre-flushing. Use extract ventilation where parts are handled away from coatings machinery. Retain drain down in sealed storage pending disposal or for subsequent recycle. Wear gloves

Footnote to Figure 6a: The identified RMMs which arelisted in the column 'RMMs for communication' differ dependent on the different contributing scenarios. This is expected, as the controls typically associated with each use will vary and it is the intention of the GES to communicate those relevant to each scenario to the DU.

The process enables a distinction to be drawn between RMM information for each contributing scenario that is required to demonstrate safe use, and thatconsidered good practice as part of related industry Product Stewardship activities and indicated in blue text. This Table therefore serves as the reference point for documenting the underlying assumptions for use within the CSR and communicating more detailed information with appropriate DUs, e.g. formulators who may wish to further refine substance concentrations within a preparation and/or recommend alternative exposure controls.

The structure of the final GES (for workers) is given in Appendix 3.1 and 3.2 and is shown both in 'raw' form, detailing the coding of the standard phrases considered appropriate, but also in the form in which it is likely to be contained within the Annex to the eSDS.

Figure 6b: Determination of Required RMMS in GES development (Consumer)

Table 1: Mapping Co	ssessment -							Indicative DNEL 10 mg/kg/d	Indicative DNEL 50 mg/kg/d
Relevant Product Categories	Product sub Category Sentinels	Relvant Exposure modifiers	Comments	Substance Specific RCR (dermal)	Substance Specific RCR (oral)	Substance Specific RCR (inhalation)	Substance Specific RCR (all routes)	RMMs for communication - Consolidate into GES or e-SDS (Black text REACH advised; Blue text recommended)	RMMs for communication - Consolidate into GES or e-SDS (Black text REACH advised; Blue text recommended)
Consumer Uses of Coatings									
PC1:Adhesives, sealants	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	Use in a well ventilated space (0.1x). Equivalent to 3-5 acph	15Kg daily use of 30% most unlikely.	0.02	0	1.35	**1.37**	Open doors and windows to provide natural ventilation. Wash any residues off skin after use. Do not use more than 750g on any day.	Open doors and windows to provide natural ventilation. Wash any residues off skin after use. Do not use more than 3.75Kg on any day.
	Glues, hobby use			0.00	0	0.12	**0.12**	No RMMs identified.	No RMMs identified.
PC4:Anti-freeze and de-icing products	Removers (paint-, glue-, wall paper-, sealant-remover)	5% dermal absorption most relevant for HCSs	2Kg daily consumer use of 30% most unlikely. 500g assumed	0.06	0	2.7	**2.76**	Open doors and windows to provide natural ventilation. Wash any residues off skin after use. If using for more than 2 hours then use RPE	Open doors and windows to provide natural ventilation. Wash any residues off skin after use.
PC5: Artists supply and hobby preparations	Finger paint, face paint			0.06	0.068	0.00	**0.13**	No RMMs identified.	No RMMs identified.
PC9:Coatings and paints, fillers, putties, thinners	solvent rich, high solid, water borne paint	100% not realistic for HCSs. 30% assumed.	1.3Kg daily consumer use of 100% most unlikely. 0.5Kg assumed	0.07	0	0.495	**0.57**	Use in a well ventilated area. Wash any residues off skin after use. Where more than 100g used, then open doors and windows to provide additional ventilation	No RMMs identified.
	waterborne latex wall paint	50% not realistic for HCSs. 5% assumed.	3.75Kg daily consumer use most unlikely. 2Kg assumed	0.01	0	0.24	**0.24**	Use in a well ventilated area. Wash any residues off skin after use. Where more than 1000g used, then open doors and windows to provide additional ventilation	No RMMs identified.
PC10:Building and construction preparations not covered elsewhere	Removers (paint-, glue-, wall paper-, sealant-remover)	100% not realistic for HCSs. 30% assumed.	25Kg daily use of 100% most unlikely. 2Kg assumed.	0.07	0	1.80	**1.87**	Use in a well ventilated area. Wash any residues off skin after use. Where more than 100g used, then open doors and windows to provide	Use in a well ventilated area. Wash any residues off skin after use. Where more than 500g used, then open doors and windows to provide

Footnote to Figure 6b: It will again be observed that the identified RMMs differ dependent on the different contributing scenarios. This is expected, as the controls typically associated with each use will vary and it is the intention of the GES to communicate to the DU those controls that are relevant. It can also be seen that the process enables a distinction to be drawn between information for each contributing scenario that needs to be communicated as a direct result of the REACH CSA, and which directly relates to default assumptions used within the TRA exposure prediction model, and that which might also be considered beneficial in assisting any safe use e.g. via industry Product Stewardship activities.

This Table therefore serves as the reference point for documenting the underlying assumptions for use within the CSR and communicating more detailed information with appropriate DUs e.g. formulators who may wish to further refine substance concentrations within a preparation and/or recommend alternative exposure controls The structure of the final GES (for consumers) that it is likely to be contained within the Annex to the eSDS. is given in Appendix 3.3 and 3.4.

To be completed for the environment

5.5. COMPILE INFORMATION INTO THE REACH GES TEMPLATE (GES PROCESS STEP 5)

Figures 6a and 6b show the process through which the GES is constructed via a CSA. The GES process also places an equal importance on the effective communication of this information in the narrative form. Appendix 3 contains examples of the narrative GES for the uses shown in Figures 6a (industrial use of coatings) and 6b (consumer uses of coatings). These take the form of the ES that might be expected to be contained within the Annex of any eSDS.

The manner in which Tables 1 and 2 are structured is key to the efficient generation of GESs. The title of the 'contributing scenario' represents a standard phrase that is easily translatable and will be readily recognisable across relevant DU groups. The RMMs and OCs that are associated with each PROC/PC are distinguished between those that specifically derive from the application of REACH processes (and which are shown in black font) from those where the M/I (or M/I association) may wish to convey product stewardship information (and which are shown in blue font and enclosed in square brackets). **It is emphasized that the inclusion of recommended product stewardship information is not a requirement under REACH. To avoid potential confusion with Downstream Users, such advice is recommended to be included within the main sections of the e-SDS and not within the ES Annex.**

Both types of RMM/OC are described by a series of standard phrases that are chosen to align with the nature of the combination of RMMs/OCs for any situation that have been identified as constituting the basis for safe use (and which are selected from a library of such phrases, see Appendix 4). This not only ensures consistency between the language of different GESs, but also improves the efficiency of M/I systems for eSDS communication (recognising that the ES will need to be translated into the relevant EU languages for the countries into which it is sold) and aids in the onward communication of the ES. For example, provided the RMMs and OCs are associated with a defined set of standard phrases/codes, then it is possible for DUs to readily identify and transmit relevant ES information in a manner that maintains the integrity of the ES and, where required, is able to adapt the phraseology for particular DU conditions/jargon/ etc. (see also Section 6 for further details).

Because the basis by which the GES for human health and the environment differs (both in the mechanics of the CSA and in the nature of the information included in the ES), it is also necessary to combine the relevant human health and environmental GES into a common form for inclusion in the CSR and eSDS. The title of the GES holds the key to how this step is accomplished: the title determines both the characteristics of the human health exposures (worker or consumer) and the nature of the emissions (local or regional). Figure 6d illustrates this relationship i.e. industrial uses are only linked with exposures to workers and related emissions are characterised at the local level, whereas professional and consumer uses are evaluated using information that allows an assessment to be made of the regional/local exposure concentrations.

Figure 6d: Integrating GES information for health and the environment

GES Title	Sector of Use	Population	Environment
Use as a chemical feedstock	Industrial	Worker	✓ (local)
Use in road and construction activities	Professional	Worker	✓ (regional)
Use of cleaning agents	Industrial	Worker	✓ (local)
Use of cleaning agents	Consumer	Consumer	✓ (regional)

The GES therefore comprises a set of assumptions that describe the various activities and circumstance of use (as they affect the environment) that constitute the general use of the substance/product within a specific sector. This is illustrated in the examples shown in Tables 1 and 2 which describe part of the life cycle of a typical (moderate volatility) alcohol used as a industrial cleaning agent. It can be seen that the use of the substance by industrial and professional groups involves a series of tasks, ranging from receiving and transferring solvents, their use in contained or open equipment, through to spraying formulations of the solvent, as well as associated maintenance activities. Thus while the GES is aimed at sectors of the industry (as most chemicals and chemical formulations tend to be targeted at particular uses by certain groups), it actually consists of the aggregated ESs for the various component tasks/ activities (further described under Section 5.5).

Developing a GES is therefore not a simple task. It requires implementing a process that that involves both M/Is and DUs and is capable of:

- Reliably mapping the circumstances where exposures/emissions occur across the supply chain
- Confirming the mapping (and terminology) in an initial dialogue between the M/I and DU
- Using this information to evaluate the integrity of the RMMs commonly encountered for the substance being marketed/registered
- Iterating the RMMs and OCs where the risks are shown to be unacceptable
- Compiling and finalising the ESs for the identified tasks/activities (including ensuring the RMMs and OCs are described in terms consistent with those expected by REACH
- Aggregating the ESs for the relevant tasks/activities within a sector of industry into a composite GES which is shared with DUs for checking that it is understandable

Although Part D of the IR&CSA TGD makes provision for the development and communication of ESs based largely around Use Descriptor codes alone, feedback from many DUs has shown that the GES is more readily understood at the DU level than the communication of a series of ESs for the component tasks (which are often seen by many DUs as 'abstract' and 'remote'). For suppliers of substances in dispersive use with extended supply chains where the need to minimise unnecessary communication within the supply chain is critical, then GESs offer an attractive alternative to ESs. They demand a greater investment of effort upfront, but this is likely to be rewarded by a reduced level of unnecessary communication from DUs. On the other hand, for M/Is with short supply chains or which target effect chemicals to niche applications, then the value of GESs may not be as obvious and specific ESs may be a solution.

5.6. DEFINING THE BOUNDARY OF RELIABLE APPLICATION (GES PROCESS STEP 6)

The final step in the process of GES development is to define the boundary within which the GES can reliably be applied and which is referred to as its "applicability domain". Each type of GES will require a statement covering, as appropriate, workers, consumers and the environment, and which will enable the user to readily ascertain the boundary conditions within which the GES is capable of managing the risks. Such boundary conditions might generally include the different classes of chemicals to which the GES applies (in terms of hazardous and physico-chemical properties) and relevant concentration ranges. Examples of such statements are shown in Appendix 2 together with further guidance on the elements that may need to be considered when developing such statements.

5.7. CONVERTING THE GES INTO A SUBSTANCE-SPECIFIC ESS (GES PROCESS STEPS 7 AND 8)

While the development of the GES represents an efficient process through which the resources and knowledge of M/Is and DUs can be brought together, REACH requires the Registration of specific substances. So while the GES can be seen to represent a set of conditions in which risks are safely managed for a hypothetical substance, for the Registration of a substance as part of the Chemical Safety Report, it is necessary to confirm the veracity of the GES for the properties of the specific substance (i.e. the particular DNEL, PNEC, volatility, etc.). Converting the GES into a substance-specific ESs and CSA for Registration and customer communication takes place in 2 stages.
The identified GESs represent the minimum number which can be identified that usefully and efficiently describe the uses of the substance across the life cycle.

5.7.1. SELECTING THE RELEVANT GESS

For the Registration of the substance, the M/I selects the relevant GES to form the basis of their substance-specific Registration. To do this the M/I will need to have a knowledge of their supply chain and, specifically, whether the chain is considered to differ from that which has been mapped as part of the GES activity for the generic supply chain. Assuming there are no differences, then the M/I selects from the GES library for the sector the relevant GESs (which will be determined by the area of use and the particular substance hazard and physicochemical properties) to form the basis of the substance-specific Registration.

The M/I will then need to amend the GES and supporting CSA documentation as required (e.g. by transforming into the desired format for CSR reporting, including details of any changes such as alterations to risk characterisation ratios, etc.) and incorporate the result within their Chemical

Safety Report. In this way the GES can be efficiently transformed to form the substance-specific ES, but with the knowledge that the ES will also be consistent (in the nature of the advice and language) with similar substances from that supply chain.

5.7.2. MATCHING THE SUBSTANCE-SPECIFIC ES TO THE PRODUCT NAMES

For many supply chains, DUs receive substances as branded products rather than as the named substance. In order that the ES for the product accurately reflects that for the Registered substance, the M/I must match the substance-specific ES to the relevant M/I product names. This should be a relatively straightforward to achieve via a simple exercise of mapping substance names to product names. In situations where the final ES for the product has not originated from a GES (which has already undergone extensive review by DU groups), then it is advisable for the M/I to make available the product ES for review by representative customers pending finalization and inclusion within e-SDS.

For multi-component products, it is recommended to develop the product ES in line with the DPD-Plus methodology. In all instances, M/Is are advised to follow the supply chain communication model recommended by CEFIC, FECC and DUCC in seeking feedback from their Downstream Users (and which is illustrated in Appendix 1).

6. Development of GES by DU Groups

In addition to any M/I developing a GESs for his substance/product, GESs can also usefully be developed by other groups. Indeed, there is obvious merit in industry sector and trade groups considering the development of GESs for their sectors, as they serve to:

- Provide a library of common standards for operational and exposure/emissions controls that are accepted across the sector
- Provide the ability to integrate sector specific jargon or technical language into the GES, thus increasing its access and understandability by DUs
- Provide a common basis for unifying ES communication throughout the supply chain i.e. M/Is are able to develop ESs, based on those authored by DU groups, which ensure the M/I obligations are met with the minimum of necessary communication with individual DUs, but whilst ensuring the ES is likely to be relevant and useful for both any formulator or downstream user.
- Potentially assists those M/Is (and, in particular, the SIEFs/consortia that such M/Is are likely to be part of under REACH) who supply substances/products to the sector to develop and communicate ESs for their substance/product that align with those that are already 'commonly used and understood' within the sector
- Enable DU groups to identify where there is value in initiating complementary GES activities for the sector

6.1 Exposure Scenarios and Safety Data Sheets

Article 31.7 of REACH states that “Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet...”.

When considering the format of the ES information to be included in the Annex to the eSDS, it is important to recognise the different objectives and target audiences of the ES information included in the CSR and the eSDS. The target audience of the ES information in the CSR is primarily the “technical expert” and the Regulatory Authorities, consequently the level of detail required is very high. In contrast, the target audience of the eSDS is the HSE department of the Downstream User (DU).

Although some DUs may be large companies, a large number will be SMEs (small and medium sized enterprises) and have limited manpower and financial or technical (risk assessment, occupational hygiene, safety, etc.) awareness/capability. So there is a need for clear and concise communication of only the relevant information in the eSDS that is necessary for ensuring safe use and handling. Over-complicated presentation and inclusion of unnecessary technical details can serve to undermine the communication process.

There also exists a very real diversity within the chemical industry from small-volume speciality chemicals supplied to a limited number of customers for very specific uses to commodity chemicals manufactured in tens to hundreds of thousands of tons per annum and supplied to widespread, dispersive industries. So, while it may be feasible to communicate a comprehensive, DU application-specific ESs in the Appendix of the eSDS for chemicals with just one or perhaps a handful of applications, it would be impractical to do this for commodity chemicals with their many tens to hundreds of distinct DUs. Whilst customer specific eSDS could be proposed for some small volume or limited use chemicals this would be impractical for commodity chemicals with their typically extensive and complex supply chains.

Although comprehensive, DU application-specific ESs are likely to be necessary for some 'high risk' situations and that detailed ESs will need to be included in the CSR (when performed by M/I in the framework of registration or by a DU in the situation of performing his own CSA/CSR), it is evident that some degree of grouping and/or generalisation of ESs could be adopted for most chemicals. The extent to which ESs can be grouped or generalised will depend upon how comparable they are in terms of the key exposure parameters, RMMs and Operational Controls (OCs).

6.2. SECTOR-INITIATED GESS

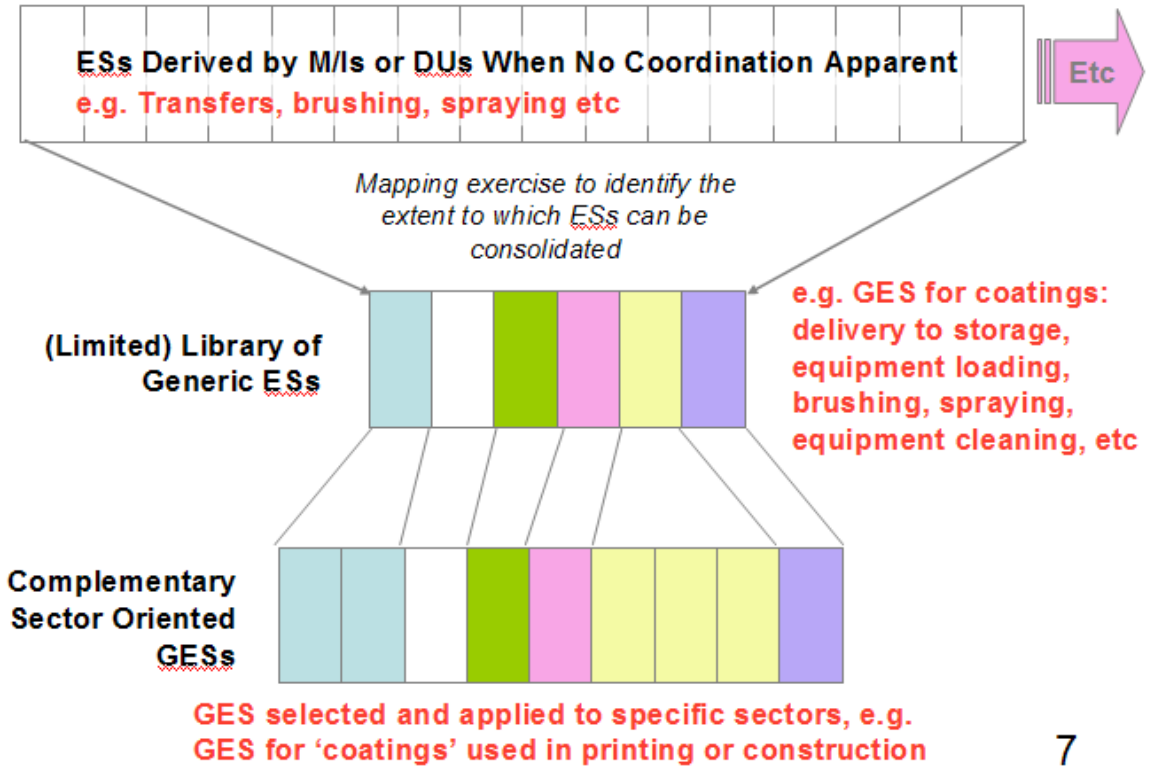
Following the discussions between the M/I and DU groups, there may also be a wish by DUs to refine the basic GES to provide sector-authored GESs for different trades etc within the sector. For example, while it may be possible to develop a GES describing the RMMs and OCs necessary to deliver the safe industrial use of a solvent as a coating, there may be a desire to develop separate GESs for screen printing and can coatings [both of which are industrial coatings activities but where the technical language of the sectors differ, as do the nature of the formulated products containing solvents that are handled in these sectors].

In a similar manner to that by which any M/I develops their GESs for their substances, trade associations and sector groups can also apply a similar process to the activities covered by their sector and the substances/formulated products that are typically encountered within it. In many respects, this process should be slightly easier for trade associations, as they can be expected to already have a good and representative knowledge of the sector without the need to confirm their understandings with DUs. However, in following the process outlined in Sections 5.1- 5.4, sector associations should bear in mind the following considerations:

- That the format in which the GES is developed should be consistent across different sectors. Clearly, the nature of the advice may differ, but consistency of format is required to facilitate the generation of ES by M/Is supplying substances/products to different sectors
- That the language used within the GES should relate to that which is common in the sector, but it needs also to be firmly based on the standard codes for each RMM and OC, in order that the language for complementary advice elsewhere in the supply chain remains standardized, i.e. the specific language of any RMM advice may change, but the substance of the advice remains constant for equivalent risks.
- That additional GESs will clearly build from the 'basic' GES, depending on level of risk that they are expected to manage. Similarly, for any use, there may be a need for more than one GES, dependent upon the range of substances/mixtures that are likely to be commonly encountered.
- That the applicability domain of each GES needs to be clearly described. Appendix 2 provides guidance on how this may be accomplished. However, it should be noted that in the case of DU/sector-initiated GESs, each GES will require a separate domain statement which will enable the user to readily ascertain the extent to which the GES is capable of managing the risks associated with different classes, concentrations and types (in terms of relevant physical chemical properties) of substances and/or preparations. The statement may also need to cover associated safety, health and environmental elements.

Some DU/F groups will consider the basic GES to be appropriate whereas other groups may determine that several complementary GESs best serve that sector. In this respect it is important to note that these sector GESs will be delivered as part of the eSDS for the formulated product and not as part of the eSDS for the substance. Figure 7 below schematically shows how the above considerations may evolve:

Figure 7: Development of sector-based GES



A major advantage of this approach to the creation of the GES is that, because the GES can be developed and structured around groups of substances or products (as characterised, for example, by a 'maximum' DNEL and/or PNEC or range of physical-chemical properties) for which the GES is applicable, it will accommodate 'minor variations' in the Classification and Labelling (or technical specification) of substances/products in the supply chain e.g. slight differences in the classification of similar supplied products. It is also able to provide useful risk management advice to DUs in advance of the REACH phase-in dates for a substance, based upon the assumption that there is a relationship between the classification and the required level of risk controls.
Appendix 3 contains several examples of GESs that have been developed as a consequence of supply chain dialogue between M/Is and DUs. Although their format differs slightly, they all show several characteristics that highlight the value of the GES as an efficient form of DU communication:

- They focus on communicating the measures necessary to manage risks in an understandable form. To achieve this, the main focus of the GES is on those steps required by the DU to manage risks.
- The language used aligns with terminology that is familiar to DUs at both the technical and sectoral levels.

The GES may include hyperlinks to other relevant sources of guidance. This enables the brevity of the GES to be maintained without constraining information flows to those who would require it. Indeed, it is possible to envisage that the GES could be condensed further if hyperlinks were also included to the substance CSR (necessarily sanitised for business confidential data) if this were to be hosted in a suitable location.

7. Format and Content of the GES

The IR&CSA TGD foresees the possibility that both 'full' and 'abbreviated' forms of ES may be developed. The 'full' ES that would support the CSR and an 'abbreviated' form that would be communicated within the Annex to eSDS.

The form of the GESs shown in Appendix 3 aligns more with the 'fuller' format of the TGD. However, certain information may not be needed within the ES that forms part of the eSDS as it may already be communicated elsewhere within the eSDS. Although the GES contains narrative for most sections, where these do not exist the basis for the GES, i.e. the CSA formed from Tables 1 and 2 of the Microsoft Excel®-based spreadsheet format, provide the necessary supporting information for formulators and other DUs to fulfil their obligations under REACH e.g. developing ESs for formulations or undertaking scaling.

Following on from this, a GES library (see section 6) may be structured to provide access to both the narrative GES and its supporting 'CSA' to cater for both DUs who simply want to a. obtain an understanding of the conditions and circumstances under which a substance or group of substances can be safely used with risks controlled, or b. have access to the underlying basis for the decisions.

8. GES Libraries

Cefic recognizes that there is value to be gained in making available the outputs of GES development from different sectors into a common ‘library’ and has set up a task force with the following objectives:

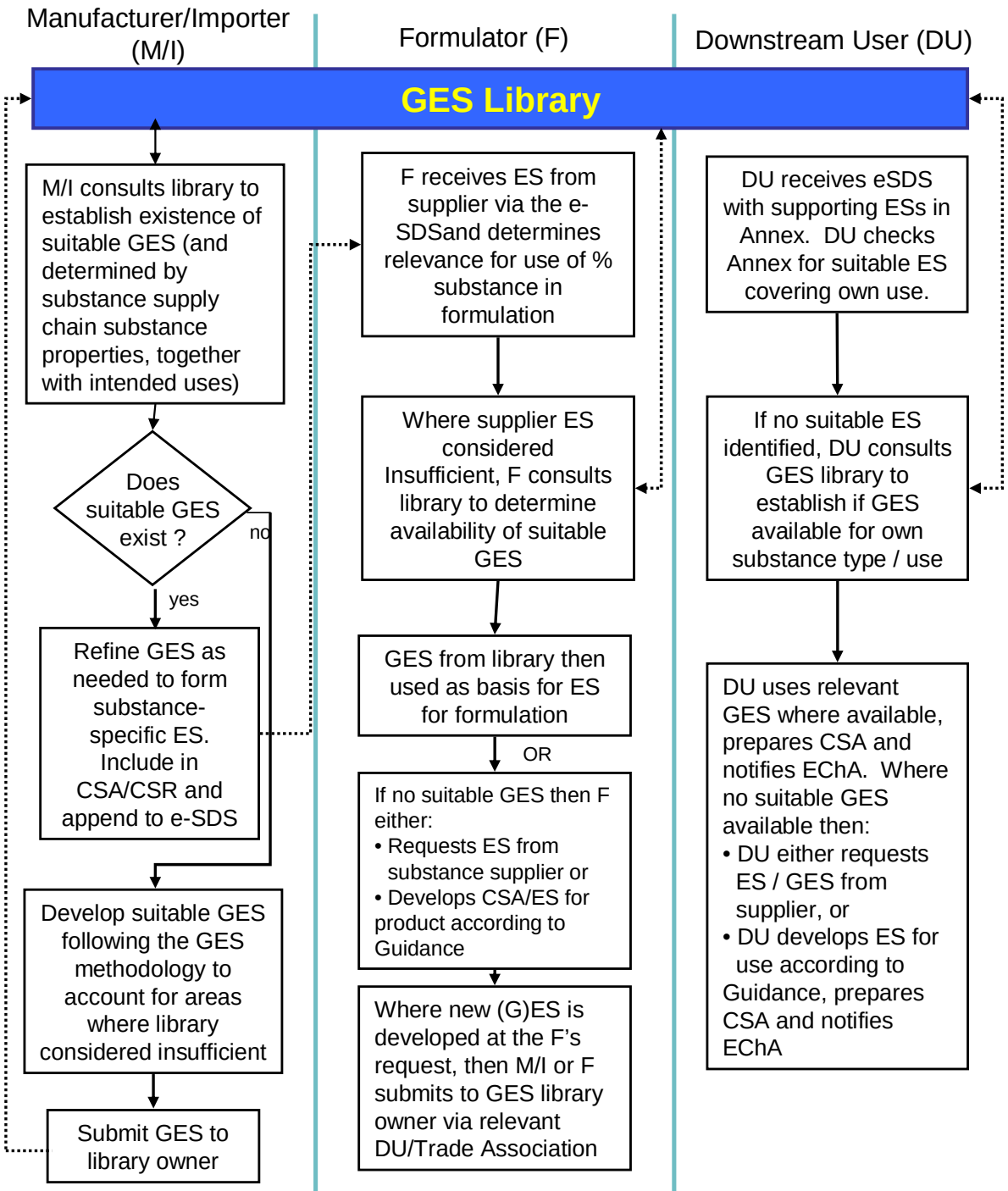
- To support the development of ES across industry
- To support consistency and efficiency of ES development
- To facilitate availability of information

The library aims to be a resource for M/Is, Formulators and DUs by providing a mechanism to:

- introduce work efficiencies e.g. the underlying premise for the library is that substances possessing similar properties and hazards represent similar risks when handled under similar conditions of use. For such substances, similar GESs should be suitable as a start, subject to review and refinement.
- make available information that describes how the human and environmental risks can be managed for uses of defined classes of chemicals.
- provide access to information that may not be communicated as part of the eSDS but which forms part of the underlying CSA for the substance e.g. how RMMs may differ for varying concentrations in use or, for late phase-in substances, where reliable information on close analogues of the substance may be already available in the library.
- allow DUs and others to gain access to information that assists them in ensuring safe use in advance of receiving an updated e-SDS from a Supplier
- The libraries will be publicly available via the Cefic website.
- The GES concept may also be applied to preparations such that DU associations representing formulators would be able to develop comparable GESs for typical groups of preparations e.g. based upon representative frame formulations for the identified uses. The resulting GESs may also be incorporated into the library for sharing.

Figure 8 provides an overview of how the GES Library may be used by each Actor in the supply chain (M/I, Formulator, Downstream User).

Figure 8: Use of GES Libraries by Supply Chain Actors



9. Summary

Generic Exposure Scenarios represent an effective and efficient way to communicate understandable risk management advice in a manner that meets the requirements of REACH. This is reflected in the process by which GESs are developed and constructed, which is specifically structured to account for the varying needs of different M/Is and DU groups. Moreover, the nature of the process, requiring a partnership of M/I and DU groups, not only ensures the communication of relevant and consistent information across supply chains, but also provides an amenability to be integrated into company (both MI and formulator) IT systems for the authoring and provision of Safety Data Sheets.

Although any GES presents significant benefits in themselves, the real value arises from when M/Is and DUs work together in partnership to develop GES libraries for a sector and/or supply chain. Such libraries constitute a bridge to the "information gap" that a reliance on SDS systems alone can create. Although SDSs are communicated to purchasers of substances, the individual user of the substance may not always have ready access to the (current) SDS. Furthermore, the phase-in periods associated with REACH will compound this 'knowledge divide' for those substances that have been Registered and those that haven't.

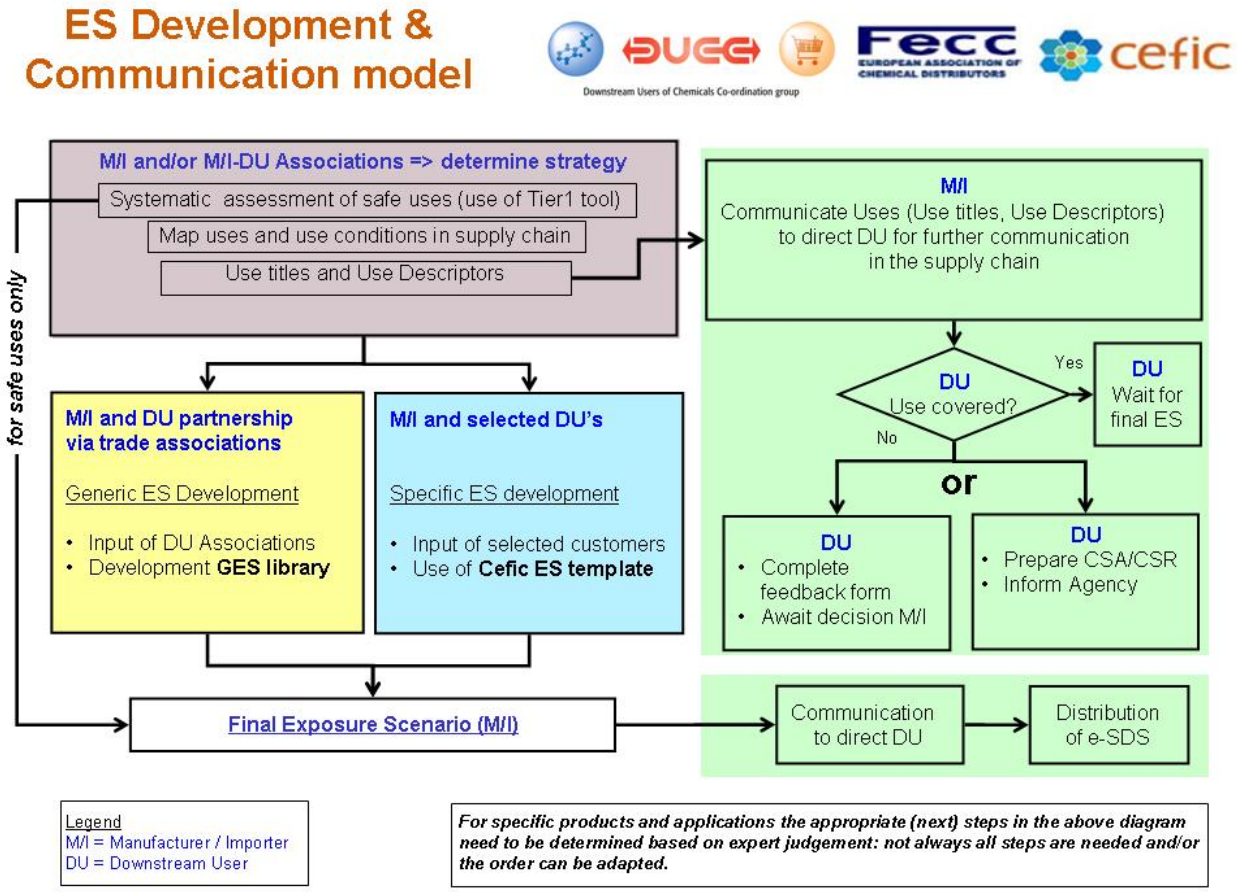
One of industry's challenges, amongst the range of activities required for successful REACH registration, will be to ensure that such libraries are generated well in advance of the Registration deadlines, not only in order that SIEFS and Consortia can build from them (to ensure consistency in the nature of communicated RMM advice for substance registrations), but also so that DUs are able to access relevant knowledge resulting from REACH activities before it's formal communication as part of any process of substance registration (and which can be further complemented by supporting product stewardship initiatives from M/Is or DU sectors).

10. References

- ECHA Technical Guidance Document: Information Requirements & Chemical Safety Assessment (IR & CSA) – http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1240853462
- ECETOC TRA Version 2, European Centre for Ecotoxicology and Toxicology of Chemicals, Avenue E. Van Nieuwenhuyse, 4 – Box 6, B-1160 Brussels, Belgium
- Cefic website http://cefic.org/templates/shwPublications.asp?HID=750

Appendix 1: Communication Flows for the Development of Exposure Scenarios

Figure 9: Workflow diagram for Exposure Scenario development and communication



The CEFIC supply chain communication flow chart for ESs recognises that the nature of the ES may differ dependent on the nature of the supply chain. It incorporates a process for the development of Generic Exposure Scenarios as addressed in this document, and also a process for the development of Specific Exposure Scenarios (SES).

In contrast to the GES process, the development of ESs following the SES process is particularly useful for substances with relatively short supply chains (e.g. speciality applications) or supply chains lacking well structured sector organizations. They are developed by the M/I in dialogue with DU selected representative customers.

Both forms of ES offer advantages and drawbacks and it is for the M/I to determine what form of ES is considered best for the type of substance they supply. Whatever the form, however, it is important, not least because all forms of chemicals are likely to be handled by DUs (and especially formulators), that the ES is constructed along similar lines and described using the common phraseology (see Appendix 4).

Appendix 2: Definition of the Applicability Domain

There is no set process for defining the boundary within which the GES can reliably be applied to support GES selection. Rather, the applicability domain statement needs to represent a succinct and visually accessible summary of the key information that will enable the DU and/or formulator to readily ascertain the extent to which the GES is capable of managing the risks associated with different classes, concentrations and types (in terms of relevant physical chemical properties) of substances and/or preparations. It will also need to include key considerations necessary if scaling is to be applied (although the extent of these is uncertain as the tools available to support scaling are limited). The statement may need to be extended to cover other safety, health and environmental considerations for some classes of substance. An example statement is shown in Figure 13 below.

A.2.1: Health and Environmental Hazards

Substance: Low volatility solvent Life cycle stage: Worker (Industrial); SU3 Area of application: Uses of coatings Process Categories Covered: PROC1, PROC2, PROC3, PROC7, PROC8a, PROC8b, PROC10, PROC13		
Validity Domain	Typically Characterised By	Typical Substances/ Mixtures Not Covered
Human Health (workers)		
DNEL : 10ppm (8 hour)	Simple aliphatic solvents (except those containing n-hexane); simple alcohols and esters	R43, R42
Moderate volatility	Liquids with a vapour pressure of < 300 hPa and used in processes operated at ambient temperature	Liquids having V.P > 300 hPa and processes operated at > 50oC
Applicable for solvent content up to 50%	N/a	Preparations having solvent content >50%
Assumes a basic level of good occupational health practice is adopted	Covers the regular supply and laundering of work clothing; provision of washing and changing facilities; eating and smoking is undertaken in areas separate from the workplace; provision of general ventilation to the workplace	
Environment		
PNEC : > 50ug/l	To be further defined how this part would be completed	
Assumes a basic level of responsible environmental protection practice is adopted		

Figure 10: Describing the Validity Domain of the GES (Industrial Use of a Solvent)

Assumptions underpinning how the applicability domain is defined include:

- The area of reliable application of each GES (its 'applicability domain') is described by unambiguous reference to the title and by linkage to the extent to which the GES is capable of managing the risks associated with different classes, concentrations and types (in terms of relevant physical chemical properties) of substances and/or preparations.
- For the solvents sector, GESs would not be developed for high risk activities. The RMMs required to effectively manage such risks are such that they are best addressed within 'tailor made' ESs for the activity and not through any GES.
- That for any type of GES, there is often likely to be more than one variation of the GESs i.e. to adequately account for common differences in industrial practice such as the quantities of material used; the predominant nature of the uses (open, closed) or users (professional, consumer, etc.)
- Although the risks are determined by reference to the DNEL or PNEC, and these value also help to characterize the domain, e.g. via use of systems for control banding and similar that are likely to be commonly encountered and familiar with DUs in the sector

A.2.2: Physico-chemical Hazards

In addition to the human health and environmental concerns, REACH requires that effects from at least the following physicochemical properties are also addressed, where activities are not covered by the SEVESO II Directive for the prevention of major accidents:

- Flammability
- Explosivity
- Oxidizing properties

General good practice advice should be incorporated already within existing Safety Data Sheets under Chapters 6 Accidental Release Measures and 7 Handling and Storage. As part of the development of the Generic Exposure Scenario potential impacts resulting from these properties should be taken into account in developing the overall controls, e.g. use of intrinsically safe electrical appliances where potentially flammable/explosive atmospheres may be present, earthing of equipment when there is potential for build up of static electricity during the transfer of flammable liquids.

When up-dating the SDS to incorporate requirements for REACH it is advised to carry out a comparison of existing guidance on controls to minimise risks from these physico-chemical hazards against any potential additional risk identified in the applicable GES(s) and up-date as required. It may be appropriate to reference specific controls within the Exposure Scenario where particular emphasis is considered important. It is suggested that this is tested as part of the development of a library of GES.

Appendix 3: Illustrative Examples of GESs

Figures 4a - 7c illustrate how a GES is developed, starting with an initial mapping of the uses of a substance, through to a stage that evaluates the risks and identifies those measures that may be necessary to control risks. However, this information is in a form that is unsuitable for routine communication to DUs as part of the Annex to the eSDS. To achieve such an objective, it is necessary to 'transpose' the CSA information into a narrative GES form. The ESVOC activity has shown that this is a critical step. Not only does the manner in which the information is communicated need to reflect the nature of the OCs and RMMs identified in the CSA, but the GES must be constructed in a manner that is understandable for the DU.

The examples exhibit a number of key features:

- They are constructed in the form standard phrases that directly relate to the relevant OCs and RMMs identified in the relevant part of the CSA (see also Appendix 4).
- For several of the RMMs, the phrase describes the expected level of control in terms of common sector technologies rather than in strictly quantitative terms which DUs may not readily understand. Sometimes, these phrases also address the management expectations that may be considered appropriate to support an identified RMM. This concept is further explained in Appendix 4.
- They often further cluster /condense the information contained in Figures 6a/6b where this would lead to repetition within the narrative GES
- That GESs are developed separately for human health and the environment but are integrated into a final consolidated GES based upon the GES title (see Appendix 5 for examples of titles)

Appendix 3.1: Industrial uses of coatings (DNEL $_{worker, systemic}$ = 10 mg/kg/d).

The following example shows how the final form of the GES that has been constructed from the information shown in Figures 4a, 5a and 6a for human health. The form of the GES follows the recommendations of the IR&CSA TGD. Those OCs and RMMs that are germane to the successful management of health risks are listed for each element of the use cycle for the type of use (in this case industrial use of coatings).

The scope of the GES is provided and those OCs and RMMs that are considered 'good practice' are distinguished in blue text and contained in square brackets. N.B. these do not directly result from the CSA but have been identified as part of the mapping and/or DU dialogue and hence M/Is may wish to consider passing on this information incorporated within the main sections of the SDS.

Substance: Low volatility solvent (OEL/DNEL = 1-10 ppm)

Life Cycle Stage: Worker (Industrial) - SU3

Area of Application: Uses of coatings

Process Categories Covered: PROC1, PROC2, PROC3, PROC7, PROC8a, PROC8b, PROC10, PROC13

Scope of process	Covers the industrial use of coatings (paints/decorative coatings, inks, adhesives, etc), both by direct application and for the manufacture of articles e.g. via dipping, and includes bulk delivery to storage; loading products from drums and kegs/cans; exposures during industrial use (including spraying, printing, dipping, brushing and other manual tasks); drying and storage of finished products; equipment cleaning and waste disposal.
Duration and frequency of use	Covers daily exposures up to 8 hours (unless stated)
Product specification	Covers use to 100%
Physical form of product	Liquid, vapour pressure <0.5 kPa
Maximum amount per time or activity	Covers volumes up to xxx (note: linked to environmental risk assessment)
Other operational conditions of use	Assumes use at not > 20oC above ambient. Assumes a good basic standard of occupational hygiene has been implemented
Risk management measures	Human health Material transfers : Handle substance within a closed system. [Clear transfer lines prior to decoupling. Remotely vent displaced vapours.] Drum/batch transfers : Ensure workplace is well-ventilated. [Use drum pumps.] Wear suitable gloves (type EN374) if prolonged skin contact likely. [Avoid spillage when withdrawing pump.] Pouring from small containers : Ensure workplace is well-ventilated. Wear suitable gloves (type EN374) if prolonged skin contact likely. Spraying : Carry out in a vented spray booth. [Ensure that air flows to the operator, then past the work activity, to the discharge point.] Wear a respirator conforming to EN140 with Type A filter or better. Wear suitable gloves (type EN374), coverall and eye protection. Printing : Ensure workplace is well-ventilated. Provide extract ventilation to points where emissions occur e.g. rollers, blankets. Wear suitable gloves (type EN374) if prolonged skin contact likely. Dipping, immersion and pouring: Ensure workplace is well-ventilated. Provide extract ventilation to points where emissions occur. Wear suitable gloves (type EN374) if prolonged skin contact likely. Avoid manual contact with wet work pieces. Manual applications e.g. brushing, rolling : Ensure workplace is well-ventilated. [Use long handled brushes and rollers where possible.] Wear suitable gloves (type EN374) if prolonged skin contact likely.

	Small package filling : Handle substance within a predominantly closed system provided with extract ventilation. Fill containers/cans at dedicated fill points supplied with local extract ventilation. [Put lids on containers immediately after use. Deal with spills immediately.] Drying and storage : Use ventilation to extract vapours from freshly coated articles/objects. [Avoid manual contact with wet work pieces.] Equipment maintenance : Ensure work area is well-ventilated. [Transfer via enclosed lines.] Wear suitable respiratory protection (conforming to EN140 with Type A filter or better) and gloves (type EN374) if regular skin contact likely. [Retain drain downs in sealed storage pending disposal or for subsequent recycle.] Environment – To be completed
Waste related measures	Dispose of waste solvent or used containers according to local regulations.
Prediction of exposure	When following the recommended Risk Management Measures and Operating Conditions, then expected exposures are unlikely to exceed the relevant DNEL/PNEC. For scaling please refer to www.xxx

Appendix 3.2: Industrial uses of coatings (DNEL $_{worker, systemic}$ = 10 mg/kg/d).

The following example shows how the final form of the GES shown in Appendix 3.1 has been constructed using a defined set of standard phrases and where 'free text' is limited. This approach is amenable to ready translation into other EU languages and incorporation within company and proprietary safety data sheet systems. The structure and benefits are explained in further detail in Appendix 4.

Substance: Low volatility solvent (OEL/DNEL = 1-10 ppm)

Life Cycle Stage: Worker (Industrial) - SU3

Area of Application: Uses of coatings GES5

Process Categories Covered: PROC1, PROC2, PROC3, PROC7, PROC8a, PROC8b, PROC10, PROC13

Scope of process GT1	Covers the industrial use of coatings (paints/decorative coatings, inks, adhesives, etc), both by direct application and for the manufacture of articles e.g. via dipping, and includes bulk delivery to storage; loading products from drums and kegs/cans; exposures during industrial use (including spraying, printing, dipping, brushing and other manual tasks); drying and storage of finished products; equipment cleaning and waste disposal.
Duration and frequency of use GT2	Covers daily exposures up to 8 hours (unless stated) OC1
Product specification GT3	Covers use to 100% OC2
Physical form of product GT4	Liquid, vapour pressure <0.5 kPa OC3
Maximum amount per time or activity GT5	Covers volumes up to xxx (note: linked to environmental risk assessment)
Other operational conditions of use GT6	Assumes use at not > 20oC above ambient. OC6 Assumes a good basic standard of occupational hygiene has been implemented. OC7
Risk management measures GT7	Human health Material transfers CS3 : Handle substance within a closed system.E47 [Clear transfer lines prior to decoupling E39 Remotely vent displaced vapours] ENVT17 Drum/batch transfers CS8 : Ensure workplace is well-ventilated E48; [Use drum pumps] E53; Wear suitable gloves (type EN374) if prolonged skin contact likely PPE15. [Avoid spillage when withdrawing pump] C&H16 Pouring from small containers CS9 : Ensure workplace is well-ventilated E48 Wear suitable gloves (type EN374) if prolonged skin contact likely. PPE15 Spraying CS10 : Carry out in a vented spray booth E57. [Ensure that air flows to the operator, then past the work activity, to the discharge point.] E7 Wear a respirator conforming to EN140 with Type A filter or better. PPE19 Wear suitable gloves (type EN374), coverall and eye protection. PPE20 Printing CS11 : Ensure workplace is well-ventilated E48. Provide extract ventilation to points where emissions occur e.g. rollers, blankets E54,E55 Wear suitable gloves (type EN374) if prolonged skin contact likely. PPE15. Dipping, immersion and pouring: CS4 : Ensure workplace is well-ventilated E48. Provide extract ventilation to points where emissions occur E54; Wear suitable gloves (type EN374) if prolonged skin contact likely. PPE15. Avoid manual contact with wet work pieces EI18 Manual applications e.g. brushing, rolling CS13: Ensure workplace is well-ventilated E48. [Use long handled brushes and rollers where possible] E58. Wear suitable gloves (type EN374) if prolonged skin contact likely. PPE15. Small package filling CS7 : Handle substance within a predominantly

	closed system provided with extract ventilation E49 Fill containers/cans at dedicated fill points supplied with local extract ventilation; E51 [Put lids on containers immediately after use.] E9 [Deal with spills immediately.] C&H1 Drying and storage CS12: Use ventilation to extract vapours from freshly coated articles/objects E56 [Avoid manual contact with wet work pieces] EI18 Equipment maintenance CS5 : Ensure work area is well-ventilated E48. [Transfer via enclosed lines] E52 Wear suitable respiratory protection (conforming to EN140 with Type A filter or better) and gloves (type EN374) if regular skin contact likely. PPE18 [Retain drain downs in sealed storage pending disposal or for subsequent recycle.] ENVT4 Environment – To be completed
Waste related measures GT8	Dispose of waste solvent or used containers according to local regulations. ENVT12
Prediction of exposure GT9	When following the recommended Risk Management Measures and Operating Conditions, then expected exposures are unlikely to exceed the relevant DNEL/PNEC. For scaling please refer to www.xxx

Appendix 3.3. Consumer uses of coatings (DNEL $_{consumer, systemic}$ = 10 mg/kg/d).

In a manner similar to Appendix 3.1, the following example shows the final form of the GES that has been constructed from the information shown in Figures 4b, 5b and 6b for the consumer uses of (solvent-based) coatings and for a volatile substance (>10Pa) and an indicative DNEL $_{consumer, systemic}$ of 10 mg/kg/day. The form of the GES only covers human health. Appendix 3.5 (to be added) shows the environmental GES for consumer uses of coatings and Appendix 3.6 (to be added) shows how Appendices 3.3 and 3.5 are integrated into the final consolidated GES for both forms of risk (although an indicative form of how the environmental controls could be communicated is also shown in the example in Appendix 3.3).

Again, the format of the GES follows the recommendations of the IR&CSA TGD. Those OCs and RMMs that are germane to the successful management of health risks are listed for each element of the use cycle for the type of use (in this case consumer uses of solvent-based coatings). Of note are the form of the identified OCs and RMMs: consumer exposures will vary dependent on the quantity, frequency and duration of use, as well as other factors e.g. ventilation rates. Therefore, there will often be a range of options for controlling exposure and the specification of what might constitute an appropriate set of recommendations for any type of use (Product Category) is the outcome of the M/I and DU dialogue. For example, the use of disposable respirators is identified as a control option where more than a certain quantity might be used on any day. An alternative to this may be to restrict package sizes or further reduce the amount of the substance present within the formulated product. Those measures that are considered 'good practice' are distinguished in blue text and contained in square brackets. N.B. these do not directly result from the CSA but have been identified as part of the mapping and/or DU dialogue and hence M/Is may wish to consider passing on this information incorporated within the main sections of the SDS.

Exposure Scenario: Consumer applications to surfaces of solvent-based coatings (xx Pa) Typical DNEL (systemic) : 10 mg/kg/d Use Description (REACH):	
Sector of Use	SU21 Private Households
Chemical Product Categories	PC1 - Sealants and Adhesives PC4 - Anti-freeze and de-icing products PC5 - Artists Supply and Hobby preparations PC9 - Coatings and Paints, Fillers, Putties, Thinners PC10 - Building and construction preparations PC24 - Lubricants, greases, and release products PC31 - Polishes and wax blends
Process Categories	Not relevant
Environmental Release Classes	To be completed e.g. ERC 8c, ERC 8f
Scope of process	Covers general exposures to consumers arising from the use of XXX in household products sold as adhesives, paints/decorative coatings, sealants, polishes, lubricants, etc.
Duration and frequency of use	Consumer Covers daily exposures to XXX-containing adhesives, paints/decorative coatings, sealants, polishes, lubricants, etc. Daily exposures assumed to last 2-4 hours Environment To be completed
Product specification	Covers the use of XXX to 30% in adhesives, paints/decorative coatings, fillers and construction products; 50% in polishes, lubricants and artists supplies; and 90% in de-icing products.
Physical form of product	Volatile solvent (>10Pa)

Maximum amount per time or activity	See Risk Management Measures for any limitations on recommended quantities of use
Other operational conditions of use	Consumer Use in a well-ventilated area. Keep away from naked flames and hot surfaces. [Wash any residues off skin after use.] **Environment** To be completed
Risk management measures	Consumer Adhesives, sealants: Open doors and windows to provide natural ventilation. If using more than 500g on any day then use a disposable vapour-removing respirator (10x protection factor) Anti-freeze and de-icing products: Open doors and windows to provide natural ventilation. If using more than 200g on any day then use a disposable vapour-removing respirator (10x protection factor) Artists supply and hobby preparations: No special precautions identified Coatings and paints/decorative coatings, fillers, putties, thinners: Where more than 300g used, then open doors and windows to provide additional ventilation Building and construction preparations: Where more than 1Kg used, then open doors and windows to provide additional ventilation Lubricants, greases, and release products: Where more than 1Kg used, then open doors and windows to provide additional ventilation Polishes and wax blends: Where more than 100g used, then open doors and windows to provide additional ventilation Environment To be completed
Waste related measures	Dispose of surplus product according to local hazardous waste regulations. Dried product can be disposed of as domestic waste.
Prediction of exposure	Refer to supporting CSA detail - See GES library
Methods to check compliance	ECETOC TRA for consumers and environment. ERCs 8c and 8f: Waste water of facility is assumed to be treated in municipal wastewater treatment. Assumed capacity of the receiving environment: > 20,000 m3/d.

Appendix 3.4. Consumer uses of coatings (DNEL $_{consumer, systemic}$ = 50 mg/kg/d).

In a manner similar to Appendix 3.3, the following example shows the final form of the GES that has been constructed from the information shown in Figures 4b, 5b and 6b for the consumer uses of (solvent-based) coatings and for a indicative DNEL $_{consumer, systemic}$ of 50 mg/kg/day. This has to be contrasted to the version shown in Appendix 3.3 for a indicative DNEL $_{consumer, systemic}$ of 10 mg/kg/day. The following differences should be noted:

- The identified RMMs are less 'severe' than those identified as appropriate in the equivalent GES for a solvent with a DNEL $_{consumer, systemic}$ of 10 mg/kg/day
- That for many forms of consumer uses, no special measures are necessary beyond the general OCs and RMMs identified
- That, following the above, it might also be expected that the identified RMMs would also be less severe for consumer uses of less volatile solvents (and where inhalation exposures are considered a prime exposure route)
- Again, the form of the identified consumer OCs and RMMs can vary dependent on the quantity, frequency and duration of use, as well as other factors e.g. ventilation rates and the final choice of recommendations will be the outcome of the M/I and DU dialogue.

Exposure Scenario: Consumer application to surfaces of solvent-based coatings (> 10Pa) Typical DNEL (systemic) : 50 mg/kg/d Use Description (REACH):	
Sector of Use	SU21 Private Households
Chemical Product Categories	PC1 - Sealants and Adhesives PC4 - Anti-freeze and de-icing products PC5 - Artists Supply and Hobby preparations PC9 - Coatings and Paints, Fillers, Putties, Thinners PC10:Building and construction preparations PC24:Lubricants, greases, and release products PC31:Polishes and wax blends
Process Categories	Not relevant
Environmental Release Classes	To be completed
Scope of process	Covers general exposures to consumers arising from the use of XXX in household products sold as adhesives, coatings, sealants, polishes, lubricants, etc.
Duration and frequency of use	Consumer Covers daily exposures to XXX-containing adhesives, coatings, sealants, polishes, lubricants, etc. Daily exposures assumed to last 2-4 hours Environment To be completed
Product specification	Covers the use of XXX to 30% in adhesives, coatings, fillers and construction products; 50% in polishes, lubricants and artists supplies; and 90% in de-icing products.
Physical form of product	Volatile solvent (>10Pa)
Maximum amount per time or activity	Assumes the following quantities of use per day : carpet adhesives (1000g), hobby adhesives (10g), artists materials, de-icing products (500g), solvent-rich coatings (500g), water-based coatings (100g), construction products (100g); lubricants and polishes (250g)
Other operational conditions of use	Consumer Use in a well-ventilated area. Keep away from naked flames and hot surfaces. Wash any residues off skin after use. Environment To be completed
Risk management measures	Consumer Adhesives, sealants (carpet, tile and parquets glues): Open doors and windows to provide natural ventilation. Do not use more than 3.75Kg on any day.

	Adhesives, sealants (hobby use): No special precautions identified Anti-freeze and de-icing products: Open doors and windows to provide natural ventilation. Artists supply and hobby preparations: No special precautions identified Coatings and paints (solvent rich, high solid): No special precautions identified Coatings and paints (waterborne latex wall paint): No special precautions identified Building and construction preparations: Where more than 500g used, then open doors and windows to provide additional ventilation Lubricants, greases, and release products: No special precautions identified Polishes and wax blends: Where more than 150g used, then open doors and windows to provide additional ventilation Environment To be completed
Waste related measures	Dispose of surplus product according to local hazardous waste regulations. Dried product can be disposed of as domestic waste.
Prediction of exposure	Refer to supporting CSA detail - See GES library
Methods to check compliance	ECETOC TRA for consumers and environment. To be completed

Appendix 3.5: Example of Environmental GES for Consumer Uses of Coatings

To be added

Appendix 3.6: Example of Consolidated GES covering Health and Environment

To be added

Appendix 4: Libraries of Standard Phrases to support ES development

It is important that the information that is used to describe and populate Exposure Scenarios is standardised such that:

- the ES can be readily constructed using standard terminology and thus readily translated into other languages
- the process of construction is amenable to automation, for example via company or proprietary SDS systems
- the process of CSR evaluation by regulatory agencies remains efficient and is not hindered by non-standard terminologies/understandings
- the efficiency of DUs communications is not adversely impacted by varying format / terminology used by different suppliers/supply chains/etc
- the process by which M/Is develop ESs either by themselves or through SIEFS/Consortia is consistent across substances, uses and supply chains.

Recognizing these demands, Industry Associations have overseen an activity aimed at constructing and hosting such a library, including how it is structured known as its 'taxonomy'. The Cefic Libraries Task Force is linked into this activity to support the further development and integration of standard phrases being identified as part of GES development, building on the work initiated by ESVOC as illustrated in the GES examples given in Appendix 3 and further elaborated in Section A.4.1 below.

A key requirement is to develop phrases that are readily understandable for DUs and avoid abstract forms such as ‘use an extract ventilation system having at least a 90% exposure reduction efficiency’, requiring interpretation by the DU on what might comprise an appropriate ventilation system. Some Member States already describe the different levels of effectiveness associated with various control options such as the UK HSE guidance ‘Controlling airborne contaminants at work’ 2008. These can be used to derive sets of standard phrases, covering workers and consumers, which meet the expectations of DUs and are consistent with other regulatory sources of advice.

A.4.1. Example of Generation of Standard Phrases: ESVOC Standard Phrases for GES Development

The basis for the ESVOC phrases is the existing series of standard phrases used by the UK and Germany in their systems for communicating advice on controlling chemical risks (COSHH Essentials and EMKG respectively). These UK/German phrases have then been re-arranged into a taxonomy that reflects the different elements required of an ES under REACH. Each element is then suitably coded and these phrases (and their associated codes) are then used in the development of the different GESs, and which are illustrated in the examples shown in Appendix 3.

Where suitable phrases do not exist to describe the nature of controls required, then a phrase has been identified/constructed ’by exception’ within the process of developing a GES in order to suitably fill the gap. This is particularly the case for phrases describing consumer and environmental RMMs and OCs, as there is limited structured regulatory advice in these areas. However, in such cases, use has been made wherever possible of other sources of information that DUs might currently receive in order that the language and content of the ES aligned with other information sources they may be receiving e.g. BATREF documentation. In order to share learnings and to facilitate consistency in the manner RMMs are quantified and described, ESVOC has adopted a process via which new phrases are regularly shared with the joint industry initiative in order that these can be evaluated and adopted into their library as appropriate. Similarly, as outlined in section 5.5, the basis by which the GES is described uses the existing catalogue of phrases as the start point.

Appendix 5: Example List of Identified Titles for GESs

Although an ES (or for that matter, GES) needs to be described in the form of Use Descriptors, the title given to a GES will be determined by the manner in which groups of substances are used within a supply chain i.e. the titles will invariably align with the descriptions of common process steps. This aspect is essential for the effective communication of ESs and their accessibility/understanding by DU groups. It is also important for DU formulators, as many formulated products also tend to be formulated for and targeted at these same industry sectors.

Agreeing the right title is therefore an important step in the development of a GES and is a function of discussion between both the M/I and DU interests. Such titles may vary between sectors (as sector terminology for similar processes can differ), but the intent should be to both arrive at the minimum number of titles consistent with unambiguous communication in the supply chain: while an excess of (inconsistent) titles may be able to offer improved 'specificity' for any use (and may be required in some situations where the use of a substance presents very real risks unless describe in detail), it also cause major issues for formulators who will be expected to assimilate and process the information from across different supply chains.

GES titles from the Solvents supply chain by way of illustration are given below:

Solvents (ESVOC GES Activity)

Common Title	Life Cycle Stage	General Scope
Manufacture including use as Intermediate/process solvent	Industrial	Manufacture of the substance or use as an intermediate or process solvent or extraction agents and subsequent recycling/ recovery, including material transfers, storage, and maintenance
Formulation & packing of preparations and mixtures	Industrial	Formulation & packing of mixtures in batch or continuous operations, including storage, materials transfers, large and small scale packing, and maintenance
Uses in Coatings	Industrial, professional, consumer	Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including materials transfer and spraying, brushing and other manual application tasks); and equipment cleaning
Use in Cleaning Agents	Industrial, professional, consumer	Covers the use as a component of cleaning products including pouring/ unloading from drums or containers; and exposures during cleaning activities (automated and by hand)
Use in Oil field drilling and production operations	Professional,	Oil field well drilling/production operations (including drilling muds and well cleaning) including material transfers, maintenance and disposal
Lubricants	Industrial, professional, consumer	Covers the use of formulated lubricants in closed and open systems including transfer operations, operation of engines and similar articles, maintenance and disposal of waste oil
Metal working fluids / rolling oils	Industrial, professional	Covers the use in formulated MWFs/rolling oils including transfer operations, open rolling and annealing activities, open and contained cutting/machining activities, draining and working on contaminated/ reject articles, and disposal of waste oils.
Propellants	Industrial, professional, consumer	Use as a propellant in professional aerosol products, including product disposal
Blowing agents	Industrial	Use as a blowing agent, including

		material transfers, curing, storage and maintenance
Use as binders and release agents	Industrial, professional	Use as binders and release agents including material transfers, mixing, application and disposal
Agrochemical uses	Professional, consumer	Use as an agrochemical excipient for application by manual or machine spraying, smokes and fogging.
Use as a fuel	Industrial, professional, consumer	Use as a fuel including incineration of wastes and use as a solvent in fuel additives

Appendix 7: Glossary of Acronyms

Acronym	Term
AISE	International Association for Soaps, Detergents and Maintenance Products
BATREF	Best Available Technology Reference Document
CEFIC	European Manufacturers' Association
CEPE	European Council of the Paint, Printing Ink and Artists' Colours Industry
COSHH	Control of Substances Hazardous to Health
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No Effect Level
DPD	Dangerous Preparations Directive
DU	Downstream User
DUCC	Downstream User Chemical Coordination Group
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EMKG	Einfaches Maßnahmenkonzept Gefahrstoffe
ERC	Environmental Release Category
ES	Exposure Scenario
eSDS	extended-Safety Data Sheet (including ES)
ESIG	European Solvents Industry Group
ESVOC	European Solvents Volatile Organic Compound Group (Solvents DU organisations)
FECC	European Association of Chemical Distributors
FEICA	Federation of European Adhesives Manufacturers
F	Formulator
GES	Generic Exposure Scenario
GHS	Globally Harmonised System of classification and labelling of chemicals
IR & CSA TGD	Information Requirements and Chemical Safety Assessment Technical Guidance Document
M/I	Manufacturer/Importer
OC	Operational Conditions
OEL	Occupational Exposure Limit
PNEC	Predicted No Effect Concentration
PC	Product Category
PPE	Personal Protective Equipment
PROC	Process Category
PS	Product Stewardship
RMM	Risk Management Measures
RPE	Respiratory Protective Equipment
SPERC	Specific Environmental Release Category
SU	Sector of Use Category
TRA (ECETOC)	Targeted Risk Assessment (ECETOC tool)
TGD	Technical Guidance Document