



**ADMIXTURES and REACH
EFCA INFORMATION DOCUMENT**

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Introduction

REACH entered into force on June 1, 2007. One of the fundamental changes brought by REACH is the change of responsibility from public authorities to industry in demonstrating the safe manufacture and use of chemicals. Manage the risk of chemicals and provide appropriate safety information to professional users and, as far as the most hazardous substances are concerned, also to consumers.

The first hurdle we encountered was pre-registration which was completed on December 1, 2008. The next major hurdle is the registration of the Tier 1 (> 1000 t/a) substances.

REACH imposes significant obligations on "downstream users" which include any natural or legal person in the EU using a substance for industrial or professional activity (other than the manufacturer, importer or distributor). Downstream users have to communicate with their suppliers regarding the applications or intended uses of a certain product. Suppliers must provide their customers with information on hazards and safe conditions of use. Downstream users are obliged to follow the supplier's advice on measures to control risks as provided in safety data sheets and any attached exposure scenarios. Downstream users must notify their supplier if their use is not covered by an exposure scenario, if they discover new information on the hazards of the product, or if they believe the risk management measures provided are not appropriate.

To achieve the correct level of communication up and down the supply chain, industry associations, Cefic and other industry partners/ federations have been working pro-actively to develop tools and practical guidelines to assist the whole of industry in its quest to implement REACH successfully. Various activities are currently under way:

Cefic CSR* task force

- Generic Exposure Scenario project
- Strictly Controlled Intermediates
- Use of existing data (ESR, HPV etc)
- ES for preparations
- Proposal for IT portal

VCI CSR* project

- Practical guidance
- Examples
- Extended SDS
- Libraries
- Communication of conditions of use

*CSR Chemical Safety Report

The European Chemicals Agency (ECHA) guidelines

Improved communication and better control are two of the requirements of REACH. The guidance document of the European Chemicals Agency (ECHA) is available on the ECHA website:

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm

http://echa.europa.eu/home_en.asp

To highlight the most important facts:

Exposure scenarios and chemicals safety assessments (CSA)

Aim of the CSA Process

- identify the conditions ensuring control of risks arising from manufacture and use(s) of a substance.
- prepare a set of corresponding information on operational conditions and risk management measures to be communicated to the users of the substance (for dangerous and PBT, vPvB substances) = Exposure Scenario (to be annexed to extended SDSs)
- document the assessment (including how the Exposure Scenarios (ES) were derived) in a Chemical Safety Report (CSR) for the companies' own documentation.
- submit the CSR to the authorities as part of the registration.

Content of Exposure Scenarios

- description of conditions suitable to ensure control of risks related to the uses of a substance during its entire life cycle. Environment, workers and consumers are to be covered. One ES can cover one or more uses.
 - operational conditions determining the exposure (e.g. duration of task)
 - practical risk management measures (RMM) suitable/needed to prevent, reduce or limit risks (e.g. exhaust ventilation)
- explanation of how the exposure estimates related to these conditions and RMM, have been derived.
- title of exposure scenario indicates for which uses it can be applied
- boundaries within which the exposure scenario is applicable.

Dual role of Exposure Scenarios

1. basis for exposure estimation (in preparing the CSA)
2. communication (CSA output, annex to SDSs)

Conditions determining exposure

Environment

Workers

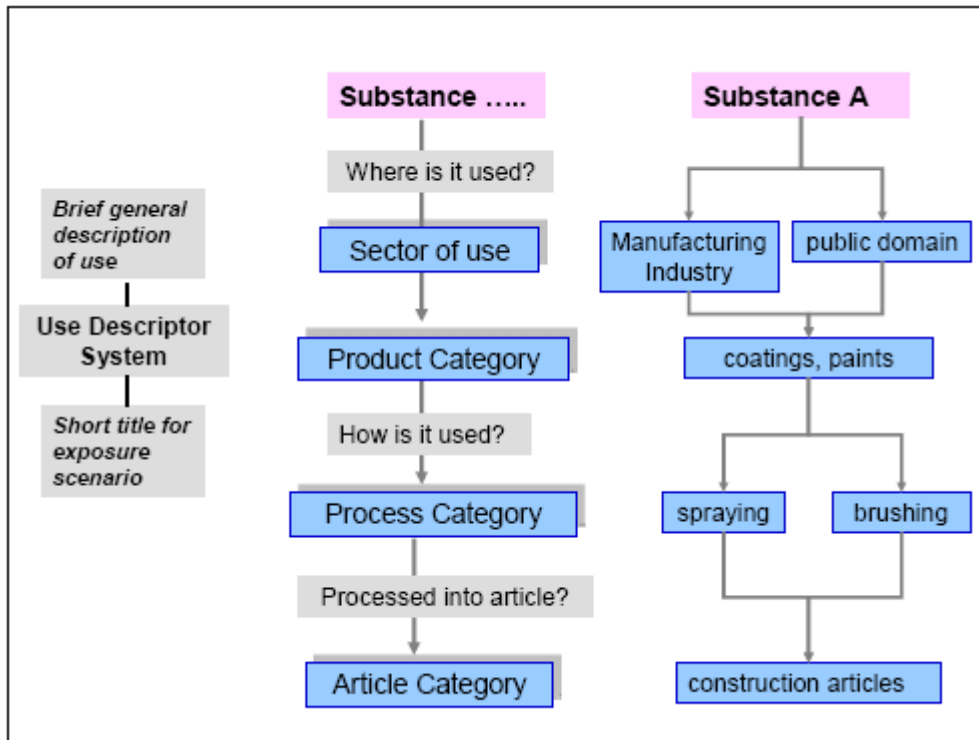
Consumers

Exposure Scenarios from the Downstream User (DU) point of view

The DU must:

- implement Operational Conditions (OC) and Risk Management Measures (RMM) communicated to him via the exposure scenarios in the SDS Annex (e-SDS)
- perform own CSA if he uses the substance outside the conditions described in the exposure scenario(s)
- communicate further down the supply chain if he is supplier

One tool to facilitate communication in the supply chain is the Use Descriptors:



Use descriptor system

- is aimed at facilitating communication in the supply chains, incl. assigning titles to ESs
- use descriptor **is not** an exposure scenario! (the use descriptor is not in itself expressing operational conditions and risk management measures)
- making a use known to the supplier (Article 37)
 - Brief description of use as a minimum (via use descriptor system)
 - Provide sufficient information to allow supplier to prepare an exposure scenario

Minimum Requirements of an ES

- contains practical and relevant OC and RMM
- specifies the boundaries of applicability
- covers health and environmental aspects of the uses/activities covered by the ES
- OC and RMM can be linked to predicted or measured exposure (health and environment)
- contains the CSA documents that risks are controlled at these exposure levels (i.e. that risks are controlled when ES is implemented)
- the information on the exposure estimation is available to downstream users (values and methods)

Industry, Federations, interested parties: Chemical Safety Report (CSR) activities

The aim of the Exposure Scenario Processes is to promote:

- consistency across supply chains for the development of Exposure Scenarios (ES)
- recognition that different types of supply chains require different approaches to ES development
- efficient supply chain communication
- development of a library of Exposure Scenarios

Two approaches have been identified:

Generic ES approach	Specific ES approach
Main Focus	Main Focus
M/I and DU Partnership via Trade Associations	M/I and Key customer iteration
Common Uses, e.g. commodity chemicals	Specialised Uses, e.g. fine chemicals
Dispersive application	Limited supply chain
Assumes some knowledge of substance handling by M/I	May have limited knowledge of substance handling in the supply chain by M/I
Groups of substances with similar applications	Single substance with specific or general applications

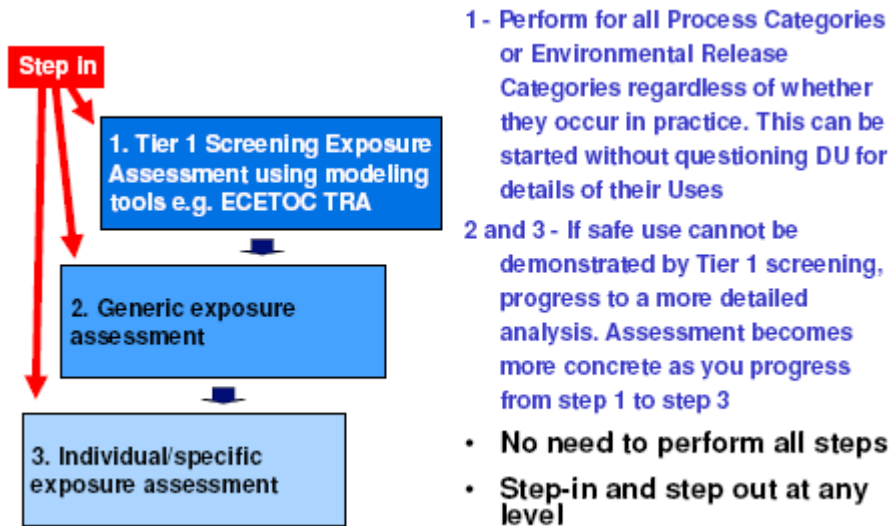
Generic Exposure Scenarios (GES)

- describes the combined Risk Management Measures (RMM) and operation conditions (OC) relevant for the safe use (EHS) of a substance or group of similar substances (or mixtures) for an area of operation in industry
- describes the OCs/RMMs appropriate for different 'risk bands' i.e. may equally be relevant for similar substances or different substances presenting comparable risks
- developed in a manner consistent with the REACH TGD based upon an initial mapping of use within the supply chain

Specific Exposure Scenarios (SES)

- SESs describe ESs for individual substances for both specific and general uses and are developed by the M/I together with DU selected customers
- SESs are incorporated directly into the M/I substance registration to support demonstration of safe use by documentation within the CSR
- SESs are transferred to an ES format for communication to customers via the e-SDS

Iterative approach to exposure assessment: 3 Tier approach (Industry & National Associations)



(Practical guide/explanation on page 9)

EFCA is actively involved in the development of Generic Exposure Scenarios (GES) for admixtures.

Generic Exposure Scenarios (GES)

- describes the combined RMMs and OCs relevant for the safe use (EHS) of a substance or group of similar substances (or mixtures) for an area of operation in industry
 - a development from similar concepts already existing in some MSs e.g. COSHH Essentials
- describes the OCs/RMMs appropriate for different 'risk bands' i.e. may equally be relevant for similar substances or different substances presenting comparable risks
 - a particular use may therefore have number of GESs which cover the different risks that the use of any substance may present e.g. low volatility/low hazard versus moderate volatility/high hazard, etc.
 - and where the limitations of application are clearly described
- developed in a manner consistent with the REACH TGD based upon an initial mapping of use within the supply chain
 - and ideally in partnership between DUs and M/Is

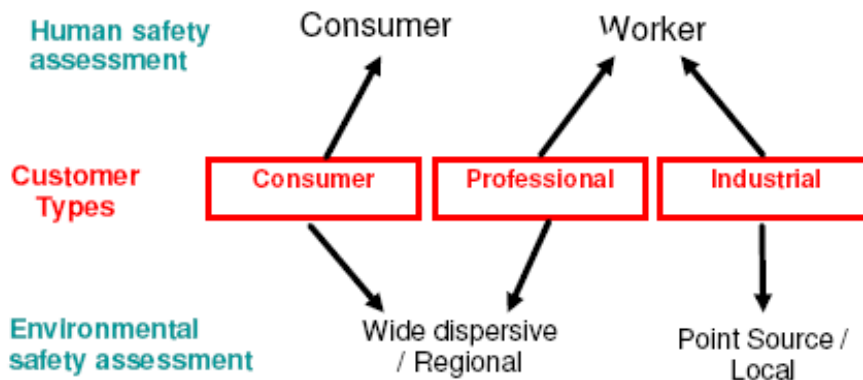
Key Characteristics of GESs

- focus on common areas of use of a (group of) substance (that can be characterised by groups of PROCs and/or PCs)
- determine simple titles (and descriptions) that describe the areas of use and that are understandable for all DUs within and across supply chains
- involve the collaboration of M/I (and/or formulator) associations and DU associations
- represent a mapping of all (or key parts of) the supply chain for a substance (or groups of substances)
- follow a process that aligns with the requirements of the TGD and delivers documentation sufficient to meet these for a CSR and/or e-SDS (subject to confirmation on the part of the registrant)
- communicate all relevant OCs and RMMs for the identified scenarios
- describe the ES according to a library of standard phrases

GES Titles Hold the Key

- one area where RIP 3.2 struggled was in determining, at practical level, how both Health and Environment guidance can be meaningfully integrated into an ES
- the basis by which the GES is created provides the ability to achieve this
- a GES does not relate solely to a task (PROC), but to the 'location' where the several tasks (PROCs) are undertaken
- by making reasonable (and transparent) assumptions relating to the location, it is therefore possible to develop GESs that can describe integrated OCs and RMMs for both health and the environment
 - the assumptions (mostly OCs) are contained in the statement on the 'domain of application'
 - the relevant RMMs are communicated together with all other considerations appropriate for managing Health and Environmental risks

Customer Types and Exposure: Assessment Approaches

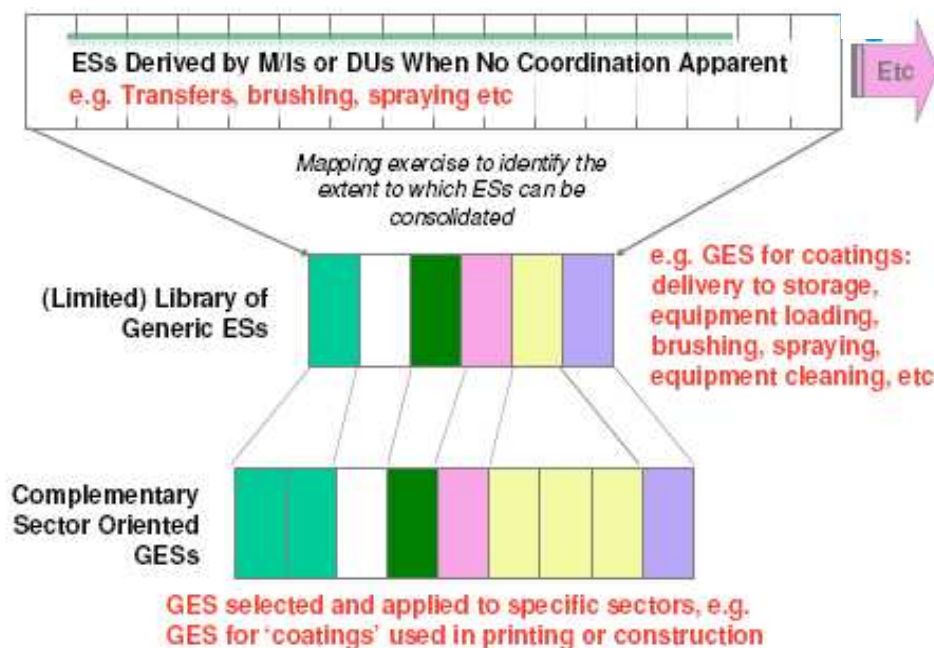


4 assessment approaches appear to be required

Benefits of Generic Exposure Scenarios

- developed in partnership between M/Is and DU representatives
 - relevance of the information to DUs. Technology, systems, language
- starting position is verification of the utility of 'existing practice'
 - no surprises; business as usual
- aim for consistency in communication within and across supply chains
 - together with simplicity and understandability
- level of detail aligned with DU needs
 - simplified ES 'highlights' in the eSDS, supported by availability of detailed ES, information as part of CSA
- minimising unnecessary supply chain communications
 - starting assumption: what is communicated is relevant and useful
 - GES format designed to be useful without need for further DU re-work
- provide basis for development of GES libraries
 - forms a resource for the development of further ESs

Use of GESs in the Supply Chain



Using the GES

- as the GES has been developed for generic uses and substances, it remains 'provisional' until it has been verified against the actual DNEL and/or PNEC of the substance
- any M/I using GESs to support the CSR for a substance will need to confirm that the OCs/RMMs are considered valid
- the GES process represents an efficient and reliable basis for the consistent identification, evaluation and communication of ES information within and across any supply chain, especially for groups of similar substances
- The tools and process for developing GESs represent an efficient and effective basis for both meeting the needs of REACH registrants and usefulness to DUs
 - the process is driven by the M/I sector but its success is a function of a successful partnership with the relevant DU sectors
 - the GES development proceeds use a format where the information is agreed on and refined at key points
 - the GESs have direct application for both substances and for the ESs of preparations
- DU sectors serve as a competent surrogate to their wider DU constituency
 - communication with individual DUs is not realistic within dispersive supply chains
 - widespread communication with DUs are only foreseen once the relevant GESs are available

Making it easier for DUs?

Exposure scenarios for preparations:

- REACH introduces the Exposure Scenario
 - REACH is substance based –preparations/mixtures are not considered
 - M/I (upstream): specific information on control of exposure/emissions of a substance under particular conditions of use
- reality:
 - varying chemical awareness among DUs
 - substances are widely handled as mixtures
- consequences:
 - totally impracticable for DU formulators to control each substance in process individually
 - inefficient/counter-productive for DU actors to receive ES on every substance in a mixture
- difficulties for DUs has been recognised by the EU
- ECHA guidance on ES for preparations

http://echa.europa.eu/doc/press/events/stks_day_20081010/stkh_esandcsa_20081013.pdf

http://echa.europa.eu/doc/reach/080417%20ECHA_08_GF_02-EN_Downstream_User.pdf

- industry assessment of ECHA guidance resulted in
 - limited practical value
 - can only use when all substances have been registered
 - could be up to 10 years before able to use!
- industry has therefore developed an alternative methodology
 - presented at Varese, May 2008
 - good reaction/support
 - approval given to gain practical experience

Industry methodology: DPD+ method

This is one way to implement the workflow in the ECHA guidance (page 115) and is **not** a substitute. It was formulated with the ECHA guidance in mind and has a similar structure

- 1st tier risk assessment
- identify the highest risk substance for each exposure/emission route
- control each “lead substance” adequately
 - de facto control of all other “same-effect” substances

Basis:

- based on Dangerous Preparations Directive (DPD) classification scheme
- enhanced with consideration of vapour pressure of volatile substances
- DPD has been chosen because its
 - well-established/well-known
 - well supported by IT/software packages

Method:

- break formulation down to constituent substances and overall individual concentrations [C]
 - for volatile components: record vapour pressure at 25°C
- for each substance record (as per DPD)
 - R phrases, grouped by exposure and emission route (inhalation, dermal, aquatic ...)
 - Annex I (specific) or II–IV (default) concentration limit [Ci]
- for each R-phrase for each substance, determine the “lead substance indicator” (LSI)
 - $LSI = C/C_i$;
 - $LSI = (VP \times C)/C_i$ for volatile components where VP = vapour pressure
- for each exposure/emission route, identify highest LSI - lead substance for that route
- Note: **not applicable to every end point**
 - CMR/PBT/vPvB/respiratory sensitization
 - expert judgement for corrosiveness

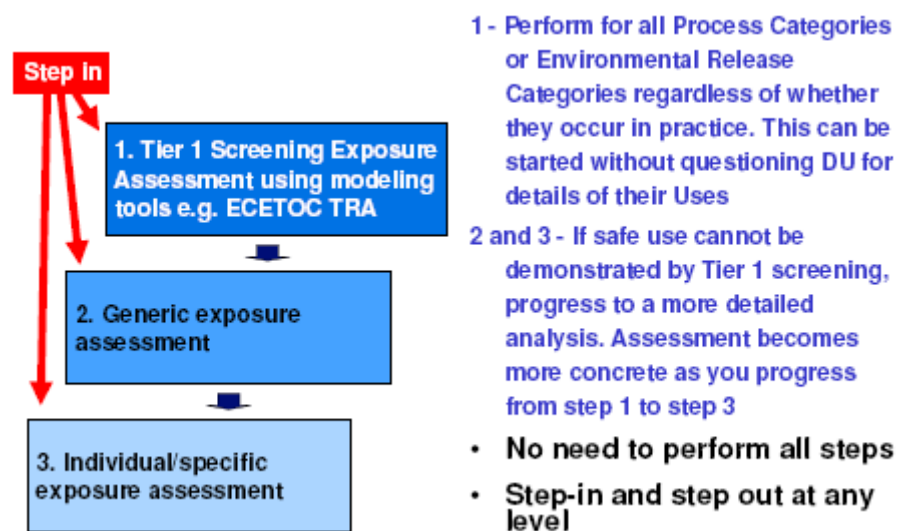
Benefits of DPD+ method

- can be used immediately
- it is flexible and adaptable

- slot in new substance classifications
 - switch to GHS, when appropriate
- copes with the ten-year transition period
 - increasing “REACH” content
- allows for step-wise improvement in ES content
- relevant to both the manufacturing and application of preparations

The Practical Guide CSR e-SDS Project

Proposed Industry Tiered approach in Exposure Assessment: 3 steps



Step 1 - Basic Exposure Assessment

- all uses can be considered in calculation/estimation
- can be performed by ECETOC TRA and / or other tools – due to the specific needs and competences of the user
- default values and input parameters can be communicated via communication platform; these conditions of use and RMM constitute ES for safe uses
- no need to do 1st step for uses where generic exposure scenario is available

Prerequisites:

- make available basic tools accessible (e. g. ECETOC TRA)
- explain link between ECHA Use Descriptors (SUs, PCs, ACs, PROCs, ERCs) and default values for conditions of use in combination with risk management measures
- M/I: communicate substance specific set-up of non-default parameters

Step 2 - Generic Exposure Assessment

- use of available Generic Exposure Scenarios (GES) is first choice
- a web-based library would allow an industry-wide standard and could be used as reference for all details that should not be included in each CSR or eSDS (“Industry Platform”)
- scenarios can be added continuously by e.g. industry sector groups
- further sector specific exposure information can be considered

Step 3 - Specific Exposure Assessment

- has to be done, if calculation with default values does not indicate that an intended use is safe and there are no applicable GESs
- is an option in each case (e.g. limited number of uses)
- is supported by available in-house and external exposure data
- use of communication templates (e.g. CEFIC ES template) is helpful
- company-specific customer communication tools can be used

Extended Safety Data Sheets (e-SDS)

Downstream communication of RMMs are done by means of the extended Safety Data Sheet. Input from VCI group to BDI activities on the update of Safety Data Sheet formats and Standard Phrases Catalogues

Output from BDI work

Standard format for the structure of extended Safety Data Sheets

- chapters 1–16: update for inclusion of new requirements
- annex: structure for exposure scenarios based on the 9 chapter proposal from the ECHA information req. guidance
- allows application of Use Descriptor System (UDS) as well as Use and Exposure Scenario (UES) matrix

Standard Phrases Catalogue

- text modules for chapters of Safety Data Sheet and Annex
- available in English and German language (free)
- input from Cefic sector groups, RMM library included in new version 10.1
- now instructional and organisational measures in addition to technical risk management measures
- to be further developed: phrases for environmental and consumer related measures

<http://reach.bdi.info/378.htm>

Downstream Users (DU) –obligations and options

1. Identify own uses as first priority
 - check hazardous substances > 1000 t/a (ECB HPV list) for **own specific uses** (common/usual uses are normally known by M/I)
 - inform M/I and sector organisations about additional uses

Upstream communication

Not necessary and not recommended that everybody communicates up stream

First choice is communication within (sector) associations on most relevant uses, typical conditions of use and RMM

- describe common set of conditions/RMM
- set link to Use Descriptors (□10 examples from Deutsche Bauchemie available)

For Tier 2 substances > 100 t/a, wait until 2012/13,

For Tier 3 substances > 1t/a: wait until 2017/18

2. Have the duty to check whether their own use is covered, if a Safety Data Sheet with Exposure Scenario (ES) has been received
 - Short Title and/or Use Descriptors can give an indication on the suitability of an ES - but relevant for the compliance check are the parameters determining the exposition, especially Conditions of Use and RMM
 - Conditions of Use of the DU will often deviate from M/I standard parameters -> scaling is required

If the DU use is not covered

- make use known to supplier or create own CSR within 12 months
- notification to ECHA within 6 months

REACH and the Regulation on Classification, Labelling, and Packaging of Substances and Mixtures (CLP)

What is CLP?

- CLP is a newly adopted Regulation
- CLP implements in the EU the internationally agreed Globally Harmonised System (GHS) of Classification and Labelling of Chemicals
- CLP builds on the Dangerous Substances Directive (DSD), the Dangerous Preparations Directive (DPD) and REACH provisions
- CLP amends REACH
- CLP will replace DSD and DPD on 1 June 2015
- CLP will impact on Downstream Legislation

Publication in Official Journal 31 Dec 2008

Entry into force: 20 days after publication in Official Journal (i.e. 20 Jan 09)

By entry into force, deletion of Annex I of DSD

Annex VI table 3.2 of CLP replaces Annex I:

Includes Annex I of DSD up to 29th ATP

30th + 31st ATP* to be added in 1st ATP to CLP

What is the transitional period in CLP?

	D/M/2008	1 Dec 2010	1 June 2015
	<i>Entry into force of CLP Regulation (20 days after publication in the OJ)</i>	<i>Applies to substances</i>	<i>Applies to mixtures</i>
Substances			
✓ Classification, labelling	DSD or CLP	CLP + DSD	CLP
✓ Classification information in SDS	DSD or CLP + DSD	CLP + DSD	CLP
Mixtures			
✓ Classification, labelling	DPD or CLP	DPD or CLP	CLP
✓ Classification information in SDS	DPD or CLP + DPD	DPD or CLP + DPD	CLP

How do REACH and CLP impact each other?

- Current DSD/DPD and new CLP: classification and labelling based on available data
- REACH will increase the data available: classification and labelling changes
- CLP changes the hazard criteria: classification and labelling (C&L) changes
- A non-hazardous substance now may become a hazardous substance later: caused by REACH or by CLP or both
- A dangerous substance now may become even more hazardous (higher classification): caused by REACH or by CLP or both
- Classification and Labelling changes caused by REACH, CLP or both **may** impact:
 - Change in Registration deadline
 - Identification of a Substance of Very High Concern
 - Complete CSA required (>10t, hazardous)
 - Restrictions

How is CLP linked to the main REACH processes?

Pre-registration: No C&L information but envisaged deadline for registration
CMR cat 1&2 (>1t) and R50/53 (>100t) = 1 Dec 2010
DSD criteria but a few cases at the margin

SIEFs:

One aim is to agree on C&L especially where there is a difference in C&L between potential registrants

Prepare for implementing CLP:

- C & L Inventory notification by 1 Dec 2010 at the latest
- For registration by 1 Dec 2010, DSD classification mandatory, CLP optional
- Registration dossier may include CLP classification if available
- For registration after 1 Dec 2010, CLP classification mandatory
- A challenge because of lack of experience
- Opt-outs because of disagreement on use of data and/or C&L

Registration

- Consider applying CLP classification criteria in CSA Hazard Assessment
- Complete CSA required if substance is hazardous or PBT/vPvB: CLP will increase the number
- Registrations already made to existing criteria should be revised once CLP applies

Evaluation

May have an influence but not specific to CLP as such

Results of testing after dossier evaluation may result in classification changes ...according to CLP

New classification may make a substance a higher priority for substance evaluation

Substance evaluation may result in a revised classification after applying CLP

- Harmonised C&L (CMRs and respiratory sensitizers)
- SVHCs

Classification and Labelling Inventory

From REACH to the CLP Regulation

Duty to notify C&L to the Inventory:

- Substances subject to registration
- Substances placed on the market as such or in mixtures and hazardous
- By 1 December 2010 at the latest

No notification required, if C&L already included in registration dossier (substances registered by 1 Dec 2010)

All other substances will need to be notified:

- Even if not yet registered
- If hazardous but out of the scope of registration
- No fees for such notifications

Impact on SIEFs from 1 January 2009 (Art 28) !

What are the proposed actions for companies?

First step is to gain understanding of CLP/GHS and its implications for your business:

- Train staff
- Change of C&L can lead to a change of duties under REACH
- Change of C&L can impact other duties under Downstream Legislation under review: keep track...

Develop an inventory of substances as such or as mixtures regardless of volumes, that are classified or subject to registration

Assess substances to be registered before 1 Dec 2010 and those subject to notification by 1 Dec 2010
Agreement on C&L to take place through the SIEF from January 2009

But for substances subject to notification and not pre-registered for example :

- consider communicating with the SIEF specific to the substance
- consider submitting to ECHA information on the substance (Art 28(7)) stating intention to join the SIEF
- consider discussing with supplier or industry association to check if agreed entry before notifying to ECHA

Conclusion

- Estimated 30,000 substances subject to REACH + other substances to enter into the Inventory
 - Estimated ~ 2,000,000 mixtures marketed : more severely classified and more classified mixtures
 - Implementing REACH and CLP/GHS at the same time is a complex operation with significant implications
 - Labelling : significant changes
 - Impact of other regions/countries implementing GHS
- **Get prepared!**

List of acronyms

AC	Article Categories
BDI	Bundesverband der Deutschen Industrie
C&L	Classification & Labelling
Ci	concentration limit
CLP	Classification, Labelling, and Packaging of Substances and Mixtures
CMR	Carcinogenic, Mutagenic, Repro tox
CSA	Chemicals Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No Effect Level
DPD	Dangerous Preparations Directive
DSD	Dangerous Substances Directive
DU	Downstream User
ECETOX	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EHS	Environmental, Health and Safety
ES	Exposure Scenario
e-SDS	extended Safety Data Sheet
GES	Generic Exposure Scenarios
GHS	Global Harmonised System
LSI	Lead Substance Indicator
M/I	Manufacturer/Importer
MS	Member States
OC	Operating Conditions
PBT	Persistent, Bio-accumulative, Toxic
PC	Product Category
PNEC	Predicted No Effect Concentration\$
PROC	Process Categories
RIP	REACH Implementation Project
RMM	Risk Management Measures
SDS	Safety Data Sheet
SES	Specific Exposure Scenarios
SIEF	Substance Information Exchange Forum
SU	Sectors of Use
SVHC	Substance of very High Concern
TGD	Technical Guidance Document
UDS	Use Descriptor System
UEC	Use and Exposure Scenario
VCI	Verband der Chemischen Industrie
vPvB	very Persistent, very Bio-accumulative

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