

Information to allow COSHH assessment



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Spirit of the law

Why we are having to do this.....

- Ensure all chemicals are identified and adequately assessed to enable communication of hazards and to enable the determination of suitable risk management measures
- Ensure that suppliers of chemical products adequately communicate in a way that relates to the use of the product
- Only actively market if uses considered to have acceptable level of risk if users follow risk management advice

..... Hopefully something we have been doing for years

COSHH basics

Control of Substances Hazardous to Health

- UK law enacting EU Directives
- Covers all industries – not just chemical industry !
- Covers all employers – responsibility to employees
- Information to be provided by chemical suppliers

This is an important part of Health and Safety at work

COSHH requirements

In practice

- Employer receives information on chemical products
 - Safety data sheet (SDS)
 - Labelling on containers
 - Responsibility to be ‘confident’ this is correct
- Employer checks proposed uses / handling / disposal*
 - Assess risk to workers from handling / use
 - Consider risk reduction through engineering controls or personal protective equipment (PPE) law enacting EU Directives
- Instructions given to employees to outline handling and risk management

* Disposal not part of COSHH, but needs to be done

COSHH advice

<http://www.hse.gov.uk/coshh/index.htm>

Excellent guidance aimed at a number of industries

- Advice on procedures
 - Excessive contact with water
 - Spraying
- Advice on product types
 - Brake fluids
 - Detergents
 - Inks
- Advice risk management
 - Types of gloves, goggles etc

Help with COSHH

The HSE have published guides to help with understanding hazardous substances, use of protective equipment, case-studies etc

- HSE software support from COSHH essentials
 - <http://www.hse.gov.uk/coshh/essentials/index.htm>
- Further support from other organisations
 - Support from Sevron <http://www.sevron.co.uk/>

Working with COSHH

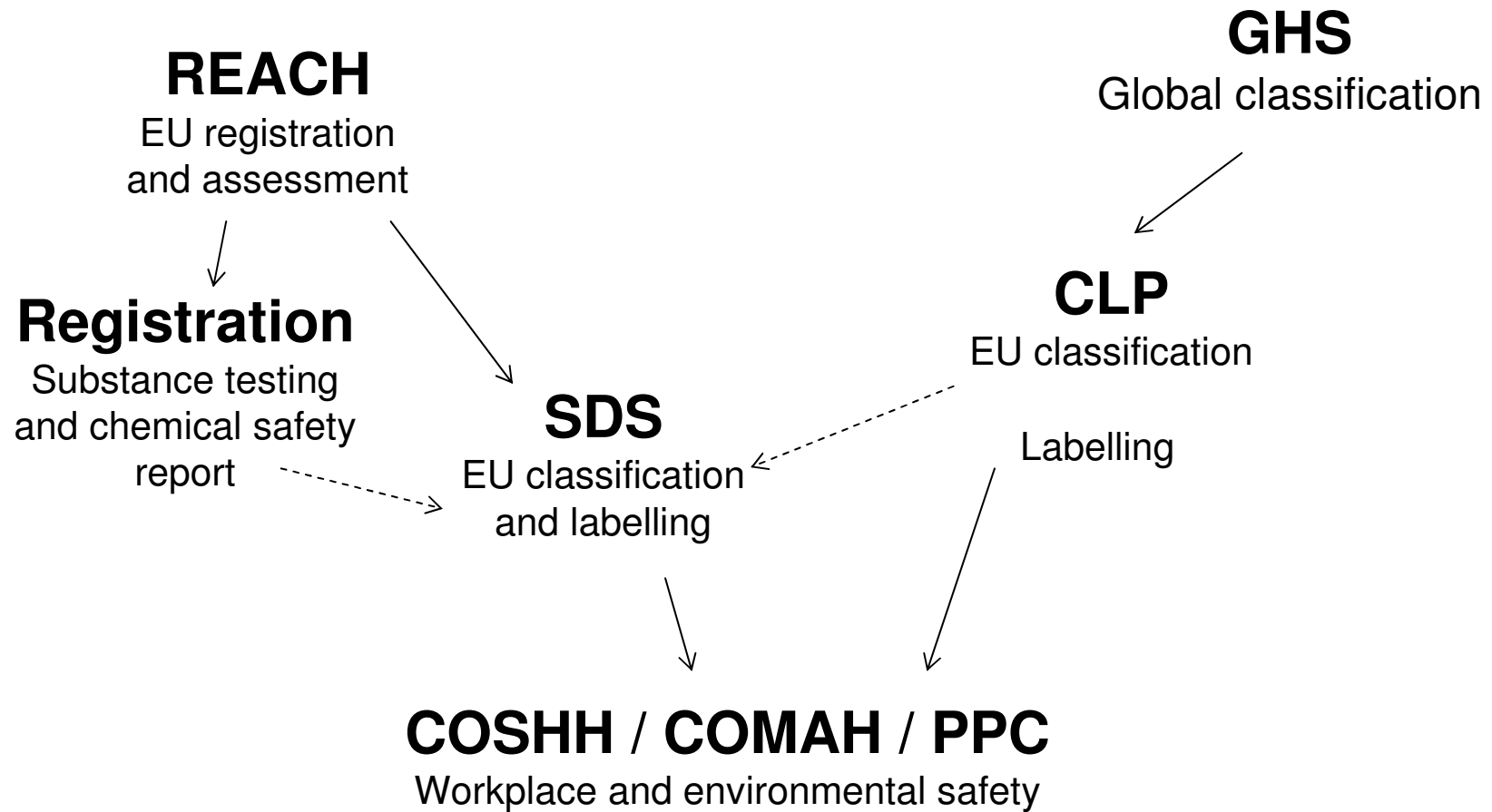
COSHH is getting more complex

- Monitoring incoming SDS / data
- Understanding data
- Reading labels and educating staff to understand new symbols

REACH and CLP will provide assessors with an unprecedented amount of data to ‘help’

As with many ‘good ideas’ like REACH and CLP, the hardest part is administrating systems and keeping up to date

Linking legislation



Duties of recipients of chemicals

- Consider all information provided by the supplier
 - Act on this to help protect your workers and the environment
- To have confidence in the supplier's information
 - Assess quality and certainty factors of received SDS
- If selling on to third parties, responsibility is assumed
 - Need to understand incoming data / exposure scenarios
- Inform supplier of adverse effects

COSHH requirement

- COSHH is the UK enacting law that covers various EU Directives on worker and workplace safety of chemicals
- New EU Regulations (REACH / CLP) will mean that the level of information available is more 'complete'
 - Translates as more complex
- Controlling exposure in the workplace is still the objective, but the data generated under REACH and communicated with CLP will allow a more targeted approach for hazardous chemicals

Supply of SDSs

SDS must be supplied for:

- Dangerous substance
- Dangerous preparation
- Substance for which there is a EU-recognised exposure limit

Not changed with REACH

Supply of SDSs

- SDS need not be supplied to the general public
- Must be provided before (or at the time of) supply of the dangerous material
- Updates pro-actively supplied
- Must include date of writing and revision date

Note that non-EU customers have same rights as those in the
EU

The 'extended' SDS

Described in REACH

- Needed from time when hazardous components are registered
- Obligatory for registrants to pass information down supply line
- Obligatory for recipients to pass information down supply line while hazardous components are contributing to hazard (eg > 1%)
- Customer pressure may be greater than regulatory needs

More later.....

Classification and labelling

EU Requirements for many years under Directive 67/548/EEC to correctly identify hazards and ensure chemicals are labelled correctly to communicate hazard

Recently, global harmonised system introduced – GHS

Based on EU system, but different symbols and phrases

Introduction on-going in EU as CLP

What is CLP

- Implements GHS in the EU
- Replaces DSD 67/548/EEC and DPD 1999/45/EC (and associated national regulations)
- Scope kept as close as possible to DSD/DPD through selection of optional building blocks, etc
- Maintains existing level of protection – EU “Leftovers”
- CLP is directly acting Regulation – no national Member State law required
- National Member State legislation still needed to define enforcement arrangements









EU CLP vs EU DSD/DPD

- The two systems are similar in that
 - they cover approximately the same hazards
 - they use mostly similar or equal classification criteria
 - they use an equivalent system of hazard communication
- The two systems are different in that
 - There are some changes in terminology, e.g. “mixture”
 - some new hazard classes are introduced
 - some labelling elements are changed
 - some classification criteria are different or use different cut-offs
 - mixtures are handled differently










CLP – most obvious changes

- New symbols (more later)
- Signal words instead of Hazard Class
- Risk ‘R’ phrases replaced by Hazard ‘H’ statements
- Safety ‘S’ phrases replaced by Precautionary ‘P’ statements
- Many more H and P Statements (3 digit numbers more difficult to remember)

Physico-chemical Hazards

		Explosive Self Reactive Organic Peroxide	
		Flammable Gases Flammable Liquids Flammable Solids Flammable Aerosols Organic peroxides	Self-Reactive Pyrophoric Self-heating Contact with water, emits flammable gas
		Oxidizing gases Oxidizing liquids Oxidizing solids	
		Gases under pressure	
		Corrosive to metals	







Health Hazards

		<p>Acute toxicity Very toxic (Fatal) Toxic</p>
		<p>Corrosive (causes severe skin burns and eye damage) Serious eye damage</p>
	 	<p>Respiratory sensitiser Mutagen Carcinogen Reproductive toxicity Systemic Target Organ Toxicity Aspiration hazard</p>
		<p>Acute toxicity Harmful Skin irritation, Serious eye irritation, Respiratory irritant Skin sensitiser Narcotic</p>

Environmental hazards










CLP vs DSD – example flashpoint

				
DSD	F + R12 Extremely flammable < 0 C Boiling < 35 C	F R11 Boiling < 0 C Bpt > 35 C	F R11 Highly flammable < 21 C Boiling > 35C	R10 Flammable 21 – 55 C
CLP	Danger Cat. 1 < 23 C Boiling < 35 C		Danger Category 2 < 23 C Boiling < 35 C	Warning Category 3 23 – 60 C
				GHS
				
				

Health and environmental hazards

- No new hazard classes, but changes in terminology may cause confusion
- New symbol for chronic effects (STOT)
- For substances, no significant extension of scope
- For mixtures, different calculation methods may change final classifications (more later)

Oral toxicity; CLP vs DSD








				
DSD	Very toxic < 25	Toxic > 25 - 200	Harmful > 200 - 2000 mg/kg	
CLP	Cat. 1 < 5	Category 2 > 5 - < 50	Category 3 > 50 - < 300	Category 4 > 300 - < 2,000 mg/kg
				
				GHS only No Pictogram

Specific target organ toxicity (STOT)

Single exposure

- Non-lethal effects after single/short term exposure
 - Specific target organ (eg liver; or blood, nerves)
 - oral, dermal or inhalation exposures relevant
 - reversible and non-reversible
 - immediate and delayed
 - not covered by other classes (eg eye irrit, repro)

Comparison with DSD





				 or nothing
DSD	Very toxic R39/28 < 25 mg/kg	Toxic R39/25 25 - 200 mg/kg	Harmful R68/22 > 200 - 2000 mg/kg	Xi, R37 (resp. irr); R67, vap. may cause drowsiness...
CLP	Cat. 1 H370 < 300 mg/kg		Cat. 2 H371 >300 – 2000 mg/kg	Cat. 3 H335 Resp. irr. H336 drows & dizz
				

Similar process for acute dermal and inhalation toxicity

Corrosion/irritation

- Skin corrosion is irreversible damage; irritation is reversible damage to the skin after 4 h exposure and 14 days observation.
- Eye irritation split between reversible and irreversible
 - Human experience
 - Extreme pH >11.5 and <2
 - Physical properties
 - In vitro testing
 - Read-across

Comparison with DSD

DSD	Causes severe burns R35	Causes burns R34		Irritating to skin R38	
	≤ 3 min	> 3 min - ≤ 1 h	> 1 h - ≤ 4 h		
CLP	H314 Causes severe skin burns and eye damage			H315 Causes skin irritation Category 2	Cat. 3
	Category 1A	Category 1B	Category 1C		
					GHS

Comparison with DSD



DSD

**Risk of serious damage to eyes
R41**

**Irritating to eyes
R36**

CLP

Category 1 H318

**Category 2
H319**

Category 2B



GHS only

Sensitisation

Skin and respiratory

- Similar criteria to DSD/DPD
 - Classifications can be read across
 - Not additive, sensitivity usually substance specific
- 2nd ATP introduces new criteria to identify most potent sensitisers
 - Lower concentration limits for most potent sensitisers

Comparison with DSD



DSD

**Xi R43 (or Xn if otherwise harmful as well)
Guinea pig or Mouse LLNA positive**

CLP

Cat. 1, H334 (no potency data)



**Warning
Cat. 1a H317
High potency**

**Warning
Cat. 1b, H317
Low potency**







Similar picture for acute dermal and inhalation toxicity

Repeat exposure STOT

	Category 1	Category 2
Pictogram		
Signal word	Danger	Warning
Hazard statement	H372 Causes damage to organs through prolonged or repeated exposure *	H373 May cause damage to organs through prolonged or repeated exposure *

*State all organs known to be affected and route of exposure if known

Comparison with DSD

		
DSD	Toxic, R48/25 <5 mg/kg	Harmful, R48/22 > 5 - 50 mg/kg
CLP	Cat. 1, H372 < 10 mg/kg	Cat. 2, H373 >10 – 100 mg/kg
		

Similar picture for acute dermal and inhalation toxicity

CMRs

Carcinogens, mutagens or toxic for reproduction

- Germ cell mutagenicity – a mutation in the germ cells (egg or sperm cells) that can be transmitted to progeny
- Carcinogen - induces cancer or increases its incidence
- Reproductive toxins - Adverse effects on sexual function and fertility in adult males and females, developmental toxicity in the offspring, effects on or via lactation

Categories







For CMR, 3 Categories

- Cat 1a = known human effects or presumed human effects based on animal data or similar substances
- Cat 1b = suspected human effects, based on clear animal data and judgement based on expert judgement
- Cat 2 = suspected human effects based on limited or possible effects in animals or expert judgement







Lot of confusion as DSD has Cat 1, 2 and 3 instead

Criteria for each class unchanged.







Carcinogenicity: comparison

			
DSD	Cat 1; R45, May cause cancer	Cat 2; R45, May cause cancer	Cat 3; R40, Limited evidence of carcinogenic effect
Effect	Substances known to be carcinogenic to man	Substance regarded as if they are carcinogenic to man	Concern for man owing to possible carcinogenic effects
CLP	Danger Cat 1A; H350 May cause cancer	Danger Cat 1B; H350 May cause cancer	Warning Cat 2; H351 Suspected of causing cancer
			




Mutagenicity: comparison

			
DSD	Cat 1; T R46, May cause Heritable genetic damage	Cat 2; ; T R46, May cause Heritable genetic damage	Cat 3; Xn R40, Possible risk of irrevisble effects
CLP	Danger Cat 1A H340 May cause genetic defects	Danger Cat 1B H340 May cause genetic defects	Warning Cat 2 H341 Suspected of causing genetic defects
			

Mutagenicity: comparison

			
DSD	Cat 1; T R60, May impair fertility	Cat 2; T R60, May impair fertility	Cat 3; Xn R62, Possible risk of impaired fertility
	Cat 1; T R61, May cause harm to the unborn child	Cat 2; T R61, May cause harm to the unborn child	Cat 3; Xn R63, Possible risk of harm to the unborn child
CLP	Danger Cat 1A H640 May damage fertility or the unborn child	Danger Cat 1A H640 May damage fertility or the unborn child	Warning Cat 2 H362S Suspected of damaging fertility or the unborn child
			







Reproductive

	Category 1A	Category 1B	Category 2	
Pictogram				
Signal word	Danger	Danger	Warning	(no signal word)
Hazard statement	H360 May damage fertility or the unborn child*	H340 May damage fertility or the unborn child	H341 Suspected of damaging fertility or the unborn child	H362 May cause harm to breast-fed children

Environment data

There is no change in this principle from DSD

Comparison with DSD

					
DSD	R50 Very toxic < 1 mg/l	R50/53 V. Tox < 1 and not RB or Kow >3	R51/53 Tox 1 - 10 not RB or Kow >3	R52/53 Harm. 10 - 100 not RB or Kow >3	R53 Poorly water sol. Not RB or Kow >3
CLP	Acute Cat. 1 < 1 H400	Chron. Cat. 1 V. Tox <1 not RB or Kow >4 H410	Chron. Cat. 2 Tox 1 - 10 not RB or Kow >4 H411	Chron. Cat. 3 Harm. 10 - 100 not RB or Kow >4 H412	Chron. Cat. 4 Poorly water sol. Not RB or Kow >4 H413
					

M-Factors (for mixtures)

L(E)C₅₀ value	Multiplying factor (M)
0.1 < L(E)C₅₀ ≤ 1	1
0.01 < L(E)C₅₀ ≤ 0.1	10
0.001 < L(E)C₅₀ ≤ 0.01	100
0.0001 < L(E)C₅₀ ≤ 0.001	1000
0.00001 < L(E)C₅₀ ≤ 0.0001	10000
(continue in factor 10 intervals)	

The 'extended' SDS

Described in REACH

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Mixtures ?

Exposure Scenario

- Required for hazardous substances
 - Where CSR has been generated
 - In practice, DUs may demand ES for all substances
- Must be relevant to real life
- Will be public on SDS
- Individual for each supplier
 - Possible to base on generic ES prepared by industry groups or SIEF
- Needs to be stand-alone and readable

Exposure scenario

Guidance from ECHA

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1307691232

Navigator provides overview

Different 'chapters' describe key activities

Part d (summary)

Covered in detail in Mod 20

First steps

- Determine use descriptors
- Follow use descriptor guidance
 - (Part D or Chapter R.12)
- Simple coding system for description of process and use
 - Sector of Use – SU
 - Product Category – PC
 - Process Category – PROC
 - Article code
 - Environmental release category – ERC

Quality of incoming information

Even when registered for REACH, there is no guarantee that the information being received is correct

- Confidence in supplier information?
- REACH registration and CSR prepared collectively
- Difficult substances?
- Data from large firms not necessarily better
- Is the Classification and Labelling Inventory helpful ?

The Chemical Safety Report

Is supposed to be

- A stand-alone document
- Summary of all hazard data,
- Reasoning for classification
- The estimated (derived) no effect levels
- Details of uses and scenarios of exposure
- Advice on practical risk management measures

The Chemical Safety Report

Is in reality

- Rushed to meet deadlines
- Extracted from IUCLID with no added data interpretation
- Exposure derived from defaults and models
- Very long and impenetrable

And probably prepared by a harassed consultant, given details of use 3 days before the deadline for submission who has probably never worked in that industry sector

Experience to date

- Many DNELs missing, but ‘waiver’ not justified
 - ‘exposure’ waiver
 - considered ‘non-hazardous by that route’
- Data summaries not readable
 - Extracted from IUCLID entries that were themselves cut and pasted from test reports with no added context
- Use details agreed by committee that may fit majority, but not all registrants
 - Exposure sections describing current practice and not advice for new users
 - Not covering specialist users

Exposure estimates

Industrial / professional / consumer ?

- Modelling methods
- Standard defaults
- Site specific data ?

Consider real use scenarios and remember that many of those writing ES have never been to a factory

It is very likely that you know more about this than a consultant

Environmental Exposure

Predicted Environmental Concentrations

- Disposal of waste water from factories
- Airborne loss (LEV ?)
- Environmental exposure from use
- Loss from domestic / non-industrial sources

Exposure Scenario must consider life cycle of substance(s) until diluted to level where not hazardous

Persistent substances of concern even when diluted

Defaults for exposure

Defaults in guidance and models

- Defaults are generally based on ‘worst case’
- Only own site data where defaults do not apply or if defaults indicate unreasonable risk
- If defaults are ‘acceptable’ use them as it is quicker than trying to do own estimates

Chapter R:16 of REACH guidance for environment

Chapter R:14 for worker exposure

Assumptions

Defaults in guidance and models

- Assume certain percentage discharge (ERC / SPERC)
 - Assume 100% loss to environment for consumer goods
- Assume specific reduction in worker exposure with gloves and coveralls
 - Models suggest 90 or 95%
- Assume efficiency of certain engineering controls
 - Models suggest 90% for LEV

These defaults will save time and allow comparison between products on multiple sites

Risk characterisation ratio (RCR)

Outcome of exposure scenario should be to confirm that if risk management measures (RMM) followed, exposure is estimated to be less than effect levels

RCR = Exposure to workers or consumers vs DNEL

RCR = Exposure to environment vs PNEC

If RMM cannot result in exposure to be below DNEL or PNEC, then use is unsuitable

Further control needed!

Scaling ?

Although not accepted by all as a mechanism for users to validate the risk management measures for their use, the term ‘scaling’ describes changing parameters to fit personal specific uses

- Tonnage
- Daily use
- Duration of exposure
- Concentration in mixtures
- Size of waste water treatment
- Size of point of discharge to surface water

Top-tips

Do not be baffled by jargon and size

- Science for CSR / ES is good
- Methods have been in place for over 20 years.
- Models are big spread-sheets using defaults
 - Pencil and paper with pocket calculator just as good
 - None are perfect
- Most CSR authors know less than factory safety and environmental managers about real life
- Most of the CSR is not worth reading
 - Advice from EA years ago was if over 20 pages, it is too long !

Good luck

Remember...

- All of industry is in this together
- Asking too much from suppliers will put up their costs
- A very long incoherent SDS is not helpful to anyone
- Ask your suppliers for help
- Good customer service includes good communication
- Concentrate efforts and resources where they are needed most
- REACH, SDS etc is ongoing and all data and documents need to be maintained

It is not too difficult to understand