REACH AND OSH INTERFACE

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- Somehow, REACH Registrants develop compliant exposure scenarios sometimes with no knowledge of the real end uses.
- And a full set of operational conditions and risk management measures that end up in the extended SDS

PROBLEMS WITH SDS

- Not always assessed to see if realistic
- Hazard data may be incorrect but recipients of SDSs don't know
- RCRs almost never provided
- Probably mostly a best guess
- Some seriously deficient
- Some ridiculously over-protective demanding all controls when OELs suggest otherwise

PROBLEMS WITH EXPOSURE ASSESSMENT

Exposure models are crude

- ECETOC TRA delivers same exposure output for all substances with BPt between 80 and 150°C (benzene to styrene)
- Models apply simplistic RMM effectiveness values that cannot be easily checked – LEV, gloves

Some modelled exposures are further amended – downwards!

REACH is internal market legislation with the aim of harmonisation

 Base is a high level of protection of health, safety and the environment when adopting measures to establish or ensure the functioning of the internal market.

- OSH legislation is social policy legislation, one objective of which is harmonisation of national laws in view of the improvement of working and living conditions.
- Directives may be adopted laying down minimum requirements for gradual implementation in various fields, including the improvement of the working environment to protect workers' health and safety.

- For the protection of workers' health and safety from risks related to chemicals at work, most relevant are Directive 98/24/EC (Chemical Agents) and Directive 2004/37/EC (Carcinogens).
- They require risks to the workers' health and safety from exposure to chemicals to be eliminated, or reduced to a minimum, by applying a framework of risk prevention and management principles including a hierarchy of preventive and protection measures.

The role of exposure in REACH – duties on Registrants

- A primary duty of registrants is to prepare a chemical safety report containing exposure scenarios.
- The REACH legal text in Annex I provides some guidance on what should be addressed in the exposure scenario.

RECOMMEND MEASURES TO CONTROL RISKS

REACH Article 14 (6)

"Any registrant shall identify and apply the **appropriate measures** to adequately control the risks identified in the chemical safety assessment **and where suitable**, **recommend** them in the safety data sheets which he supplies in accordance with Article 31."

Article 14 (6) requires registrants to **recommend** risk management measures in a safety data sheet.

REACH Annex I Section 0.7

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The main elements of the exposure part of the chemical safety report is the description of the exposure scenario(s) implemented for the manufacturer's production, the manufacturer or importer's own use, and those **recommended** by the manufacturer or importer to be implemented for the identified use(s)

An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, **or recommends** downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or **recommends** to be implemented by downstream users.

Requirement on suppliers.

REACH Article 31 (7)

Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses...

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REACH Annex II Section 0.1.2.

The information provided in the safety data sheet shall be consistent with the information in the chemical safety report, where one is required. Where a chemical safety report has been completed, the relevant exposure scenarios shall be placed in an annex to the safety data sheet.

REACH Annex II Section 0.2.1.

The safety data sheet shall **enable** users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment.

Enable = Give the means to do something

REACH Annex II Section 0.2.2

The information provided by safety data sheets shall also **meet the requirements set out** in Council Directive 98/24/EC. In particular, the safety data sheet shall enable employers to determine whether any hazardous chemical agents are present in the workplace, and to assess any risks to the health and safety of workers arising from their use.



REACH Annex II Section 8.1.5 Control banding approach

"Where a control banding approach is used to decide on risk management measures in relation to specific uses, sufficient detail shall be given to enable effective management of the risk. The context and limitations of the specific control banding recommendations shall be made clear."





REACH Annex II Section 8.2.1

The description of appropriate exposure control measures shall relate to the identified uses(s) of the substance or mixture as referred to in subsection 1.2. This information shall be sufficient to **enable the employer to carry out an assessment** of risk to the safety and health of workers arising from the presence of the substance or mixture in accordance with Articles 4 to 6 of Directive 98/24/EC as well as in accordance with Articles 3 to 5 of Directive 2004/37/EC, where appropriate

Article 37 (1) A downstream user or distributor may provide information to assist in the preparation of a registration

REACH Article 37 (5)

Any downstream user shall identify, apply and where suitable, **recommend**, appropriate measures **to adequately control risks identified** in any of the following:

- the safety data sheet(s) supplied to him
- his own chemical safety assessment
- any information on risk management measures supplied to him in accordance with Article 32 (where a safety data sheet is not required)

CONTROL THE RISKS IDENTIFIED IN THE SDS

- REACH Article 37 (5) requires downstream users to identify and apply measures to adequately control risks.
- The text is rather ambiguous, but could it be read as stating the relevance of the supplied safety data sheet is to be a source of identification of the risk – not a source of the appropriate measures.
- The identification and application of the appropriate measures is a task for the downstream user, again supporting the concept this would be done under the CAD.

WHAT TO DO?

- Annex II identifies that the downstream user is provided with supportive information for them to make their judgements in the context of Directive 98/24/EC.
- Arguably, REACH Article 37 possibly should not be read as presenting any form of strict obligation on downstream users to adopt any specific set of pre-prescribed measures to achieve control.

•That judgement is left to the assessment under the Chemical Agents Directive oand specifically applying the principles of Article 6 (2) of that Directive.

CONTROL BANDING

Control banding takes account of hazard and intrinsic properties of substance.

- For serious hazards the control banding approach defaults to specialist advice an indication of the seriousness of the effect and the need to provide a customised solution to the problem through employing recognised competent practitioners.
- It is dangerous to deploy a generic control scenario that may not be adequate or suitable for the purpose – there is too much left to chance.

• There are uncertainties:

- over the outputs from the models,
- over the selection of inputs and
- over the generic description of risk management measures that may result.

MATHEMATICAL IMPERATIVE

Exposure scenarios, generated under REACH, often are not recognised at the local level. The exposure scenarios are often born of a mathematical imperative to demonstrate compliance with the requirement to show exposures in the registration dossier are below the DNEL. There is much argument over the ability of the tools to predict with enough certainty in both accuracy and precision.

QUALITY

• ECHA seeks to improve quality in dossiers, but ...

 Recipient of SDS has little idea if advice has been quality assured – can they take the risk, particularly if mixtures?

• Often, the quality of the SDS is an unknown

CONCLUSIONS

- Read the small print
- Chemical Agents (COSHH) still the most important driver of controls in the UK workplace
- Some REACH dossiers are attaining quality through compliance check ...
- ... but you may not know which
- Mixtures bring even more uncertainty
- What is the authority for enforcing implementation of RMMs from the SDS?
- SDSs are uncharted waters caveat emptor!!



A REACH PERSPECTIVE

A window on the world or A cloak of mystery

Andrew Phillips For BOHS East Midlands Regional Meeting 06 February 2019



- A bit about hazard assessment and DNELs
- ► A bit about exposure assessment under REACH
- Communication in the supply chain

REACH: HAZARD

HAZARD ASSESSMENT 1 TONNE OR MORE (REACH ANNEX VII)

- Skin irritation or corrosion in vitro
- Eye irritation in vitro
- Skin sensitisation human evidence or in vivo
- In vivo gene mutation
- Acute toxicity

HAZARD ASSESSMENT 10 TONNES OR MORE (REACH ANNEX VIII – 2018)

- Skin irritation in vivo
- Eye irritation in vivo
- Mutagenicity in vitro cytogenetic or in vitro micronucleus
- Acute toxicity by inhalation and/or dermal
- 28-day repeated dose study
- Reproductive screening study

HAZARD ASSESSMENT 100 TONNES OR MORE (REACH ANNEX IX – 2013)

- Further mutagenicity studies depending on earlier results
- Sub-chronic toxicity study (90-day)
- Pre-natal developmental toxicity study
- Generation reproductive toxicity (maybe one or two species)

HAZARD ASSESSMENT 1000 TONNES OR MORE (REACH ANNEX X - 2010)

- Second pre-natal developmental
- Carcinogenicity study (rarely required)

 widespread dispersive use and/or evidence of frequent or long-term human exposure

 Often Generation toxicity required at this tonnage as adaptation (Annex XI) rules strictly interpreted

HAZARD ASSESSMENT ADAPTATION (REACH ANNEX XI)

- Use of existing data read across
- Weight of evidence
- QSAR structure activity relationships
- Grouping of substances
- Testing not possible
- Substance-tailored exposure-driven testing
 - No exposure/negligible exposure
 - Certain screening tests or sub-acute testing not valid

Aimed at reducing unnecessary animal testing

- DNEL (Derived No Effect Level) is a reference value used to quantify the human health risk; DNEL is the level of exposure, above which humans should not be exposed.
- In the risk characterisation, the exposure of each human exposed population is compared with the appropriate DNEL. The risk to humans is controlled if the exposure levels do not exceed the appropriate DNEL.

- DNEL is based on the non-toxic level (NOAEL/LOAEL) from the key studies
- In principle, DNEL is set for each endpoint (e.g. repeated dose toxicity, reproductive toxicity) and for each exposure route (oral, inhalation, dermal), for which a NOAEL/LOAEL is available and exposure is likely to take place



DNEL DERIVATION

Three step procedure

- Selection of dose descriptors
- Modification of dose descriptors
- Application of assessment factors for uncertainties

DNEL derivation procedure



Step 3: application of assessment factors

- Assessment factors to address uncertainties (Annex I, Section 1.4.)
- There are 6 assessment factors that will be applied to account for:
 - interspecies variability <u>allometric</u> differences,
 - interspecies variability remaining differences,
 - intraspecies variability,
 - differences in exposure duration,
 - issues related to dose-response, and
 - quality of database
Step 3: application of assessment factors

Table R. 8-6 Default assessment factors

Assessment facto	r – accounting for differences in:	Default value systemic effects	Default value local effects
Interspecies	 correction for differences in metabolic rate per body weight remaining differences 	AS ^{a, b} 2.5	- 1 ^f 2.5 ^g
Intraspecies	- worker	5	5
	- general population	10 ^c	10 ^c
Exposure	- subacute to sub-chronic	3	3 ^h
duration	- sub-chronic to chronic	2	2 ^h
	- subacute to chronic	6	6 ^h
Dose-response	 issues related to reliability of the dose-response, incl. LOAEL/NAEL extrapolation and severity of effect 	1 ^d	1 ^d
Quality of whole database	 issues related to completeness and consistency of the available data 	1 ^d	1 ^d
	 issues related to reliability of the alternative data 	1 ^e	1 ^e

 Acute – inhalation, systemic effects **x2** Acute – inhalation, local effects **Workers** Acute – dermal, local effects and Long-term – inhalation, systemic effectGeneral Population Long-term – inhalation, local effects Long-term – dermal, systemic effects •Long-term – dermal, local effects Long-term – oral, systemic effects (not relevant to) workers)

- For risk characterization, the lowest DNEL is selected (for the leading health effect) for each route of exposure, when appropriate
- DNELs are set for consumer and workers separately
- DNELs will vary greatly depending on the effect data typically, 1-10 mg/kg bw.

Some issues for me

Difficult for ultimate user to judge whether the DNEL is based on serious or less serious consequences

REACH is fine to find carcinogens, reprotoxic, mutagens – then we try not to use them in widely available chemical formulations – not refine the exposure and RMMs

Some DNELs based on poor evidence and inconsequential effect – that is what is communicated but there may be an underlying more serious effect but with a higher DNEL

Some issues for me

Does not find respiratory sensitisers – 10-100 tonne, many fine chemicals

Dose response curve - What is the consequence of over-exposure?

Most downstream users struggle to interpret the information

Very often DNEL not provided in SDS – just rote RMMs arising from modelling of exposures to create the extended SDS – too many slightly differentiated exposure scenarios. Some issues for me

Who understands DNELs?

Part of registration process – they have a clear purpose in that context

Are they reliable in the context of risk management measures?

What are end users meant to do with them?

Proposing risk management measures from afar

WHAT DID ECHA FIND

40% evaluated DNELs were wrong Selection of dose descriptor Application of non-default assessment factors Missing DNELs Inappropriate use of OELs

Example 1: Assessment factors (AF) applied in the registration compared to the default factors recommended in ECHA Guidance R.8.

DNEL		AFs applied	ECHA AFs
Worker, long-term,	interspecies allometric	4	4 (rat to human)
dermal, systemic effects	interspecies remaining	1	2.5
	Intraspecies	3	5
	exposure duration	2	6 (sub-acute to chronic)
	Quality of the data base	1	1
	Total	24	300

Example 2. The following table lists assessment factors (AF) applied in the registration compared to the default factors recommended in ECHA Guidance R.8.

DNEL		AFs applied	ECHA AFs
General population, long-term,	interspecies allometric	4	4 (rat to human)
oral, systemic effects	interspecies remaining	1	2.5
	intraspecies	5	10
	exposure duration	2	6 (sub-acute to chronic)
	Quality of the data base	1	1
	Total	40	600

Substance	DNEL mg/m ³	WEL mg/m ³
Styrene	85	435
Toluene	192	191
N-Methylaniline	0.0495	0.22
Formamide	6.6	37

Deutsche Gesetzliche Unfallversicherung Spitzenverband

DNEL list of the DGUV

ame	Data	CAS No	EC No	DNEL Inhala	tion [mg/m ³]
	Set			local	systemic
ELDEW PS-203	1		429-630-8	46,7	11,7
Electrolytes, copper-manufg., spent	1	69012-54-0	273-752-2	0,05	
Electrolytes, copper-manufg., spent	2	69012-54-0	273-752-2		5
Electrolytes, copper-manufg., spent	3	69012-54-0	273-752-2		0,004
Electrolytes, copper-manufg., spent	4	69012-54-0	273-752-2		0,05
Electrolytes, copper-manufg., spent	5	69012-54-0	273-752-2	0,05	0,05
Electrolytes, copper-manufg., spent	6	69012-54-0	273-752-2	0,5	
Electrolytes, copper-manufg., spent	7	69012-54-0	273-752-2		0,1
Electrolytes, copper-manufg., spent	8	69012-54-0	273-752-2	0,04	
Electrolytes, copper-manufg., spent	9	69012-54-0	273-752-2		0,005

https://dnel-en.itrust.de

(e	Data	CAS No	EC No	DNEL Inhal	ation [mg/m³]
	Set	i i		local	systemic
phosphate and Methyl dihydrogen phosphate and Phosphoric acid		5			
Reaction mass of Dimethyl adipate and Dimethyl glutarate and Dimethyl succinate	1		906-170-0	8,3	
Reaction mass of N-[3-(Dimethylamino)propyl]docosanamide and N-[3- (Dimethylamino)propyl]stearamide	1		913-660-8		14
Reaction mass of (1R,2R)-2,4-Dimethylcyclohex-3-enecarbaldehyde and (1R,2S)-2,4-Dimethylcyclohex-3-enecarbaldehyde	1		943-728-2		1,837
Reaction mass of 1-(3,3-Dimethylcyclohex-1-en-1-yl)pent-4-en-1-one and 1-(5,5- Dimethylcyclohex-1-en-1-yl)pent-4-en-1-one	1		944-482-9		6,2
Reaction mass of (1S,1'R)-[1-(3',3'-dimethyl-1'-cyclohexyl)ethoxycarbonyl]methyl propanoate, (1R,1'R)-[1-(3',3'-dimethyl-1'-cyclohexyl)ethoxycarbonyl]methyl propanoate and (1R*,2'R*)-(2,6,6-trimethyl-1-cycloheptyloxycarbonyl)methyl propanoate	1		607-255-2		20
Reaction mass of N,N-dimethyldecan-1-amide and N,N-dimethyloctanamide	1		909-125-3		166,67
Reaction mass of N,N-Dimethyldodecanamide and N,N-Dimethyltetradecanamide	1		944-968-0		40
Reaction mass of 2-(1,1-Dimethylethyl)-4-{[5-(1,1-dimethylethyl)-4-hydroxy-2- methylphenyl]thio}-5-methylphenyl 3-(dodecylthio)propionate and Thiobis[2-(1,1- dimethylethyl)-5-methyl-4,1-phenylene] bis[3-(dodecylthio)propionate]			940-594-7		0,137
Reaction mass of 2,6-Dimethylheptan-4-ol and 4,6-Dimethylheptan-2-ol	1	×	939-420-2		53
Reaction mass of 7,7-Dimethyl-2-methylidenebicyclo[2.2.1]heptane and (1R)-2,2- Dimethyl-3-methylenebicyclo[2.2.1]heptane and (1S)-2,2-Dimethyl-3- methylenebicyclo[2.2.1]heptane and (1S)-2,6,6-Trimethylbicyclo[3.1.1]hept-2-ene	1		945-713-6		0,933

re	Data	CAS No	EC No	DNEL Inhalat	tion [mg/m ³]
	Set			local	systemic T
Hydrocarbons, C7-C8, n-Alkanes	1		922-214-1		2035
Hydrocarbons, C9-C11, n-alkanes, isoalkanes	1		941-718-2		871
Hydrocarbons, C5, n-alkanes, isoalkanes	1		921-577-3		3000
Hydrocarbons, C9-C12, n-alkanes, isoalkanes, <2% aromatics	1		940-725-8		1500
Hydrocarbons, C8-C11, n-alkanes, isoalkanes, <2% aromatics	1		940-733-1		1500
Hydrocarbons, C13-C20, n-alkanes, isoalkanes, cyclic, aromatics (40-60%)	1		928-812-9		165
Hydrocarbons, C7, n-alkanes, isoalkanes, cyclics	1		927-510-4		2085
Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics	1		920-750-0		2035
Hydrocarbons, C8-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	1		928-136-4		330
Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, <2% aromatics	1		927-241-2		871
Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, <2% aromatics	1		919-857-5		1500
Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	1		919-446-0		330
Hydrocarbons, C6-C7, n-alkanes, isoalkanes, cyclics, <5% n-hexane	1		921-024-6		2035
Hydrocarbons, C6-C7, n-alkanes, isoalkanes, cyclics, >5% n-hexane	1		924-168-8		145
Hydrocarbons, C6, n-alkanes, iso-alkanes, cyclics, n-hexane rich	1		925-292-5		93
Hydrocarbons, C5-C6, n-alkanes, isoalkanes, <5% n-hexane	1		922-114-8		1474
Hydrocarbons, C6-C10, n-alkanes, isoalkanes, > 5% n-hexane	1		920-191-2		230
Hydrocarbons, C5-C7, n-alkanes, isoalkanes, n-hexane rich	1		930-397-4		93

HSE says

REACH identifies a Derived No Effect Level for substances (DNEL). This is a benchmark not an exposure limit. The manufacturer or importer uses this <u>DNEL</u> to identify the correct Risk Management Measures for your task or procedure the exposure scenario.

Exposure scenarios and the 'Risk Management Measures' (RMM) appear in the <u>REACH Safety Data Sheet</u> for a substance or product. <u>REACH</u> is being phased in until 2018.

By using the <u>RMM</u> in the Safety Data Sheet, you are likely to comply with the DNEL. By using good control practice such as is given by COSHH essentials, you are likely to comply with any Workplace Exposure Limit.

EXPOSURE AND REACH

REACH Annex I – the Chemical Safety Report

THE WAY WE WERE

- What was all the fuss about?
- Has exposure under REACH peaked?
- Did ECETOC TRA do its job?
- Are registration dossiers what they are?
- Unless pressure from ECHA, maybe these will not be revisited any time soon
- ▶ So if they are correct then that's fine
- ...if not we have to live with it and the consequences of poorly described exposure scenarios
- Do we know which are which?



2/7/2019

31

WHAT IS EXPECTED OF EXPOSURE **UNDER REACH**



- Rare to find exposure data how much, how good, how relevant
- ► Why?
 - Because data, if they exist, are not representative of the final exposure scenario
 - Registration dossiers provided by manufacturers or importers of substances
 - Data do not meet the REACH definition of control of risk
- Use of exposure models
 - Objections to use some are sceptical my model is better than your model, so there!
 - Validation
 - They are tools to allow registration
 - Inhalation + dermal combined exposure for each endpoint
- Final exposure scenario a funny thing
 - That set of conditions that ensure exposures below the DNEL (inhalation, dermal and oral)
- REACH registration dossiers, by definition, cannot provide final exposure scenarios that are unsafe

Includes some risk management measures and operational conditions

- PROCs Process categories
- ▶ LEV 90%
- ▶ Gloves 80%, 90%, 95%
- ▶ RPE 80% ,90% ,95%
- ► Concentration
- ► Duration

Conditions in extended safety data sheet



FINAL EXPOSURE SCENARIO

REACH Guidance R12 Use description Table R.

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

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

50 Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12: Use description Version 3.0 - December 2015

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

			1
PROC8a	Transfer of substance or mixture (charging and discharging) at non- dedicated facilities ²⁶	Covers general transferring operations of large quantities of chemicals from/to vessels, containers, installations or machinery without dedicated engineering controls in place for reducing exposure. Transfer includes loading, filling, dumping, bagging and weighing.	
PROC8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities ²⁶	Covers general transferring operations from/to vessels or containers with provision of dedicated engineering controls in place for reducing exposure: it addresses operations where material transfers are undertaken at locations that are specifically designed and operated for the transfer of larger quantities (tens of kilos and higher) of chemicals and where the exposure is primarily related to the un-coupling/coupling activity rather than the transfer itself. Such situations include tanker loading bays and drum filling. Transfer includes loading, filling, dumping, bagging.	
PROC9	Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage. This PROC can also be used to cover sampling operations.	
PROC10	Roller application or brushing	This includes application of paints, coatings, removers, adhesives or cleaning agents to surfaces with potential exposure arising from splashes. This PROC can also be assigned to tasks such as cleaning of surfaces using long-handle tools.	

COMMUNICATION IN THE SUPPLY CHAIN

What does that mean?

REACH AND OSH FOR USERS OF CHEMICALS





Strategic Objective 1

Maximise the **availability of high quality information** to enable the safe manufacture and use of chemicals

Strategic Objective 2

Mobilise authorities to use information intelligently to identify and address chemicals of concern

QUALITY AND COMPLETENESS IN THE CSR

- Quality in what sense?
 - Science
 - Presentation understandability
 - Completeness of hazard data set
 - > Description of uses ... "vague" doesn't help anybody!
 - Too many unlikely uses included
 - ▶ Too few uses for a well known substance which is widely used
 - Description of processes, jobs and tasks needs to be <u>illustrative enough</u>
 - Understanding exposure
 - > Developing proportionate, realistic risk management options
 - Connection to OHS issues



QUALITY – EXPOSURE ASSESSMENT

Generally a poorly understood area – and not just REACH! Most assessors don't have much of a clue - under REACH it is often a numerical exercise and can lead to naïve conclusions - and incorrectly specified RMMs



> Driven by models but poorly predictive in some areas

- not representative
- not conservative enough in some areas
- ► too conservative in other cases
- dermal exposure badly understood in particular
- often limited information on dermal absorption
- sometimes matters, sometimes not

Real life and modelled predictions may not coincide



It's exposure Jim, but not as we know it



ADDRESSING RISK MANAGEMENT MEASURES



ADDRESSING RISK MANAGEMENT MEASURES

Substances are not used in isolation - real workplaces need to deal with this

Q. Why is a substance controlled to a specific level?

A. For a range of reasons

- ► Known toxicity OEL or DNEL in place
- Suspected toxicity
- Unknown toxicity
- ► Local effects
- Properties other than toxicological
 - ► Flammability
 - ▶ Odour
 - ► Keep the place clean
 - ▶ Protect the product
 - ► Generic controls for a range of substances handled on site

RISK MANAGEMENT MEASURES IN CONTEXT

- Industry have a default set of approaches to handling chemicals
 - Can be quite sophisticated
 - Can be simple
 - Within the context of OHS requirements
- Much detailed regulation and advice available
- Legal framework EU Directives workplace, chemical agents, carcinogens national legislation
- Comprehensive supporting guidance to assist compliance



Health and Safety Executive

Personal protective equipment at work

Contents

5
Guidance on the Personal Protective Equipment at Work Regulations 1992 7
Citation and commencement 7
Interpretation 7
Disapplication of these Regulations 7
Provision of personal protective equipment 11
Compatibility of personal protective equipment 15
Assessment of personal protective equipment 16
Maintenance and replacement of personal protective equipment 17
Accommodation for personal protective equipment 18
Information, instruction and training 19
Use of personal protective equipment 20
Reporting loss or defect 21
Exemption certificates 21
Extension outside Great Britain 22
Modifications, repeal and revocations 22

CSR says - "Good occupational hygiene practice" - what does it mean

Schedule 2A Principles of good practice for the control of exposure to substances hazardous to health

Schedule	2A	Regulatio	n 7(7)
		(a)	Design and operate processes and activities to minimise emission, release and spread of substances hazardous to health.
		(b)	Take into account all relevant routes of exposure – inhalation, skin absorption and ingestion – when developing control measures.
		(c)	Control exposure by measures that are proportionate to the health risk.
		(d)	Choose the most effective and reliable control options which minimise the escape and spread of substances hazardous to health.
		(e)	Where adequate control of exposure cannot be achieved by other means, provide, in combination with other control measures, suitable personal protective equipment.
		<i>(f)</i>	Check and review regularly all elements of control measures for their continuing effectiveness.
		(g)	Inform and train all employees on the hazards and risks from the substances with which they work and the use of control measures developed to minimise the risks.
		(h)	Ensure that the introduction of control measures does not increase the overall risk to health and safety.

RISK MANAGEMENT MEASURES IN CONTEXT

- REACH Registrants have to anticipate downstream users are sufficiently compliant with OHS legislation - many are not.
- Addressing appropriate limits of exposure
 - unsympathetic interpretations from toxicological studies may lead to DNELs that cannot be complied with - even for quite benign substances.
- Heavy reliance on outcome of quantitative assessment of exposure
 - it's sometimes the wrong thing to do!
 - Exposure modelling distorted by need to comply with punative DNELs
- How far can manufacturers of substances go to ensure safe use down the supply chain?
| Contributing exposure scenario controllin | g worker exposure for PROC 4 | |
|---|---|-----------|
| Name of contributing exposure scenario | Use in batch process and other process (synthesis) where
opportunity for exposure arises | |
| Processes, tasks, activities covered | Use in batch manufacture of a chemical where significant
opportunity for exposure arises, e.g. during charging, sampling
or discharge of material, and when the nature of the design is
likely to result in exposure | |
| Product characteristic | | |
| Physical state | Liquefied gas | |
| Concentration of substance | Pure substance | |
| Vapour pressure | 3140 hPa | |
| Fugacity | high | |
| Amounts used | | |
| This information is not needed for assessment | it of worker's exposure. | |
| Frequency and duration of use/exposure | | |
| Duration of exposure | > 4 hours/day | Location |
| Frequency of exposure | < 240 days/ycar | Domain |
| Human factors not influenced by risk man | agement | Technical |
| Exposed skin surface | Palm of both hands (480 cm ²) | Local exh |
| Other given operational conditions affecting workers/consumers exposure | | Minimisat |

REACH Chemical Safety Report Contributing exposure scenario

Location	Indoor with Local Exhaust Ventilation (LEV)
Domain	Industrial
Technical conditions and measures to confi	rol dispersion from source towards the worker
Local exhaust ventilation	Yes
Minimisation of splashes and spills	·
Technical conditions and measures at proc	ess level (source) to prevent release
Minimisation of manual phases/work tasks, a cleaning of equipment and work area	voidance of contact with contaminated tools and objects, regular
Organisational measures to prevent /limit i	releases, dispersion and exposure
Management/supervision in place to check the training for staff on good practice, and good s work area	at the RMMs in place are being used correctly and OCs followed, tandard of personal hygiene, regular cleaning of equipment and
Conditions and measures at level of article	production to prevent release during service life
Not applicable	
Conditions and measures related to inform	ation and behavioural advice to consumers
Not applicable	
Conditions and measures related to person	al protection, hygiene and health evaluation
Suitable respiratory protection	yes
Gloves (suitable chemical resistant gloves + basic and specific activity training)	yes
Chemical goggles	yes
Face shield substance/task appropriate gloves	and full skin coverage with appropriate light-weight barrier

ADDRESSING RISK MANAGEMENT MEASURES

Generic v specific

- LEV what does that mean in practice? What about other engineering solutions?
- Gloves effectiveness -what does it mean?

Impact of local conditions

- REACH dossiers and SDSs are not a workplace risk assessment
 - but they may guide required action can't be too prescriptive otherwise not compatible with real life most of the time
 - but can give good information on physical, chemical and potency
 - ▶ if threshold, the effect may not matter the potency does
 - ▶ but needs to be understood, implemented and seen in context.
 - users may do something different and better conceptually equivalent

Uncertainties over application of PROCs

- what do they cover
- ▶ what don't they cover.
- interpretation in the context of local conditions -PROCs are at best "an impressionist image" - your mind fills in the detail