# Introduction to REACH

## IGHRC workshop
## 16th December 2009

Andy Gillies
MD, Gillies Associates Limited
Chair, BOHS REACH Steering Group

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# Agenda

- Overview of REACH
  - Key features, responsibilities and milestones
  - Industry perspective
  - **Worker**, environment, consumer aspects

- Specific issues
  - Exposure limits (DNELs)
  - Exposure modelling
  - Generic Exposure Scenarios
  - RMM efficiency
  - REACH and COSHH interface

# Acknowledgements

Some of these slides are taken from presentations given by BOHS members and others at various meetings including the BOHS/NVvA joint workshop held in Brussels on 30th September and 1st October 2009:

"REACH – Registration and Beyond: Exposure Scenarios and Safe Handling Advice"

# A brief introduction to BOHS

- The British Occupational Hygiene Society
- A multidisciplinary, learned and professional society established since 1953
- The voice of the occupational hygiene community in the UK
- An unrivalled source of information and expertise for members and non-members alike
- An examining board, through the Faculty of Occupational Hygiene, awarding qualifications in occupational hygiene and allied subjects
- For anyone with an interest in occupational hygiene

# BOHS

The Society's aim is simple:

*To help to reduce work-related ill-health*

The result is dramatic:

*A healthy worker in a healthy working environment*

British Occupational Hygiene Society

*Working for a healthier workplace*

www.bohs.org

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# BOHS Strategy for REACH

*"BOHS regarded as the hub of expertise for REACH Exposure Scenarios and Risk Management Measures"*

- ✓ Enhance and promote the science of exposure assessment
- ✓ Improve understanding and practical implementation of Risk Management Measures
- ✓ Influence ongoing development of Regulation and guidance
- ✓ Extend competence of BOHS membership in all aspects of REACH
- ✓ Increase BOHS visibility within the context of REACH

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# Overview of REACH

- **Registration,**
- **Evaluation,**
- **Authorisation and**
- **Restriction of**
- **Chemicals**

- Single system to replace 40 existing sets of regulations
- Applies to New and Existing chemicals
- Covers worker, environmental, and consumer risks
- Burden of proof on industry
- Manufacturer/importer responsible for
  - ✓ testing and assessment
  - ✓ safe downstream use and disposal

# Who is affected?

Any company ***producing, importing, using or placing on to the EU market a substance, preparation or article.***

- Not just the Chemical Industry sector!
- Duties on manufacturers, importers, article producers, distributors and downstream users
- All chemicals will have to be registered before they can be used
- It is the legal responsibility of manufacturers and importers to ensure that substances (and articles) they manufacture or place on the market are adequately controlled
- Downstream users must apply the control measures recommended

# Supply chain actors

- ***Manufacturer*** – production or extraction of substances in the natural state *[Article 3(8)]*
- ***Importer*** – physical introduction into the customs territory of the Community *[Article 3(10)]*
- ***Downstream User*** – use of a substance, either on its own or in a preparation:
  - ***Use*** means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation

***A company may have various roles in the supply chain depending on its activities, even for the same substance***

# The scale of REACH

- 2008 predictions
  - Pre-registrations 180,000
  - Substances 30,000
  - Average no. companies per SIEF 5
  - Max. no. companies per substance 30

- 2009 reality
  - Pre-registrations 2.7 million !
  - Substances >143,000 !
  - Signed up Legal Entities >65,000
  - 8000 SIEFs with >50 participants !

# For a company with 1000 high tonnage substances...

- join 1000 consortia
- agree with each one the legal provisions for data sharing, splitting costs etc.
- carry out any necessary testing
- develop Chemical Safety Assessments
- achieve consensus on the registration dossiers
- and submit them to ECHA

... all by the end of 2010

Acknowledgments CEFIC

# How REACH Will Work

- Registration
  - M/I must document that human health & environmental risks are adequately controlled in all identified uses
- Evaluation
  - EChA to review registration dossiers and CSR for compliance and animal testing proposals
- Authorisation
  - For substances of very high concern (CMR class 1 and 2, PBT, vPvB, others, e.g. endocrine disrupters)
- Restriction
  - The “missing R”; for substances where risks are unacceptable

- **European Chemicals Agency**
- **Registration above 1 tonne**
  - requires dossier of test information
  - reduced requirements for intermediates
  - One Substance, One Registration
- **Risk assessment above 10 tonnes**
  - ✓ requires detailed Chemical Safety Assessment and Report
  - ✓ Worker, environment and consumer risks

# Substances of Very High Concern (SVHC)

SVHC subject to Authorisation (*Article 57 and Annex XIV*)

- Class 1 and 2 CMR substances (*Directive 67/548*)
- PBT and vPvB substances (*Annex XIII criteria*)
- equivalent level of concern

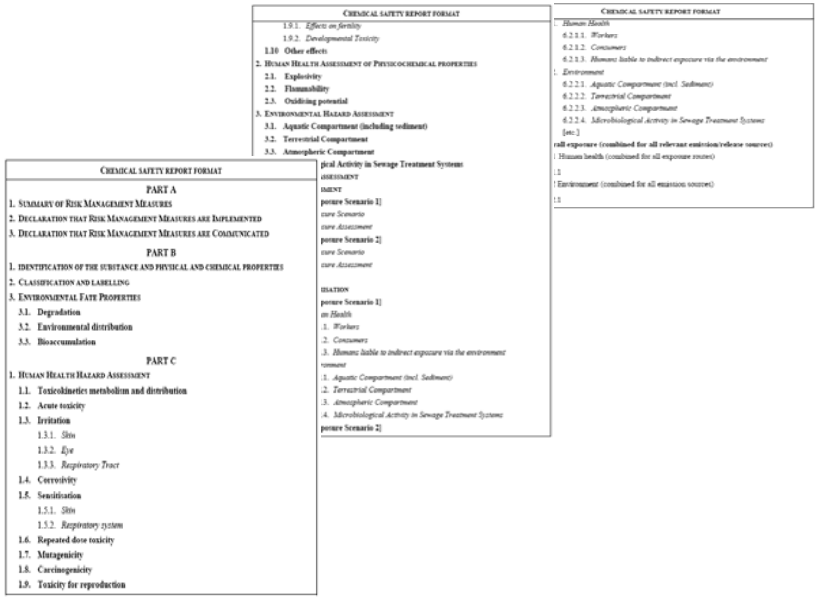
- First Authorisation list published by EChA in 2009
- Priority given to PBT, vPvB, large quantities, or wide dispersive applications
- Aim is to progressively replace SVHC by less harmful substances or technologies

# Chemical Safety Assessment (CSA)

- For chemicals > 10 tonnes per year manufacturers/importers must:
  - ✓ predict the exposures that will occur in manufacture and use(s)
  - ✓ identify the conditions that will ensure control of risks
- Prepare a corresponding ***Exposure Scenario (ES)*** to be communicated to the users in an ***extended-Safety Data Sheet (e-SDS)***
- Document the assessment in a ***Chemical Safety Report (CSR)***
  - ✓ Exposure Scenarios
  - ✓ exposure estimates
  - ✓ risk characterisation
  - ✓ Risk Management Measures
- Submit CSR to the authorities as part of the registration

# Chemical Safety Assessment

- Human health (worker, professional, consumer)
  - ✓ Evaluate data (animal data, epidemiology)
  - ✓ Decide on classification and labelling
  - ✓ Establish exposure standards
- Safety (physico-chemical)
  - ✓ Explosivity, flammability, oxidising potential
- Environmental
  - ✓ Evaluate data, including PBT and vPvB assessment
  - ✓ Decide on classification and labelling
  - ✓ Establish Predicted No-Effect Concentration (PNEC)

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# Risk Characterisation

- For worker exposure, determine residual risk to workers (after RMM implemented) by comparing exposure with the relevant DNEL or DMEL
- If ratio >1, additional RMMs required
- Perform similar calculation for:
  - ✓ all routes of exposure (especially air and skin)
  - ✓ other groups of people at risk
  - ✓ environmental risks

# One Substance One Registration

- Companies intending to register the same substance must form **Substance Information Exchange Forums (SIEFs)**
  - ✓ share existing data and studies to avoid duplication
  - ✓ identify data gaps and arrange for further studies
  - ✓ agree classification and labelling
- One SIEF for each substance and one **Joint Submission** for each
  - ✓ members must agree upon how they will work together
  - ✓ REACH (Art. 30): SIEF participants shall share costs in a fair, transparent and non- discriminatory way
- SIEF members MUST Select a **Lead Registrant**
  - ✓ the Lead Registrant submits the "joint submission dossier".

# Timeline

- 1 June 2008:
  - ✓ REACH entered into force
  - ✓ new chemicals must be registered before use
  - ✓ existing chemicals are to be phased in by tonnage
- 30 Nov 2008:
  - ✓ existing chemicals greater than 1 tonne must be “Pre-registered” or taken off-market

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- **30 Nov 2010:**
  - ✓ **register >1000 tonnes/year + CMRs Cat 1&2 or off-market**
- 31 May 2013:
  - ✓ register >100 tonnes/year or off-market
- 31 May 2018:
  - ✓ register >1 tonnes/year or off-market
- Downstream Users
  - ✓ right to inform their uses to their suppliers 1 year before the relevant registration deadline

# Specific issues

- Exposure limits (DNELs)
- Exposure modelling
- Generic Exposure Scenarios
- RMM efficiency
- REACH and COSHH interface

# Risk characterisation and Exposure Standards

- Risk characterisation required for each Exposure Scenario. Estimated exposures compared to threshold values (DNEL/PNEC).
- Risk Characterisation Ratio (RCR):
  - For Human health, Exposure / DNEL
  - For environment, PEC / PNEC
- Adequate control under REACH is defined as where RCR < 1.

# New Worker Exposure Standards under REACH

- **Derived No-Effect Levels (DNELs)**
  - ✓ May be set for different routes of exposure (inhalation, dermal) and different sub-populations
  - ✓ Assessment Factors applied to take into account uncertainties and extrapolation to humans
  - ✓ likely to be more stringent than current Indicative Occupational Exposure Limit Values
- **Derived Minimum-Effect Levels (DMELs)**
  - ✓ for chemicals such as genotoxic carcinogens where no threshold can be determined
  - ✓ a low (possibly theoretical) risk, which could be seen as a tolerable risk

# DNELs and OELs

- Where there is an existing OEL for a given substance, the registrant will be allowed to use this as a DNEL for the same exposure route (inhalation) and duration of exposure except where
  - ✓ **other exposure routes or durations** than those covered by the OEL need to be taken into account, or
  - ✓ **an OEL does not provide the level of protection required by REACH**
- Different frameworks used for setting OELs and DNELs with different 'safety factors' but the same toxicology and risk assessment principles.
- DNEL derivation is difficult, practical experience needed
- Potential for confusion when OEL does not equal DNEL

# IOELV vs DNEL: 2-(2-Methoxyethoxy)ethanol (DEGME)

- IOELV derivation

  … In the developmental study with rabbits and dermal application a NOEL of 50 mg/kg bw. was obtained. Assuming a similar (100%) absorption after oral, inhalative and dermal exposure and a 8 h inhalation volume of 10 m3 at the workplace 50 mg/kg bw. correspond to 70 ppm. For interspecies extrapolation regarding systemic effects it should be noted that presumably the metabolites of DEGME have a longer half-live in humans than in animals. As shown for 2-ethyoxyacetic acid the half-live is 6-fold longer in humans than in rats. As a worst-case approach it is assumed that the effects of DEGME are governed by the time-concentration product. The dose per kg bw for workers should therefore be accordingly lower than the NOEL of 50 mg/kg bw obtained in the animal experiment. Considering the difference in the DEGME metabolite between animals and man a factor of 5 is applied resulting in an OEL of 10 ppm.

- SEG 1994: Overall Uncertainty Factor = 5 (or 7)

- DNEL derivation

  Oral to inhalation x Rabbit to human x Variability among workers

  Overall Assessment Factor = 2 x 2.4 x 5 = 24

# DNELs for Skin

- How can skin DNEL's be interpreted:
  - Measurements on surfaces?
  - Measurements on skin?
  - Biological measurements?
  - Predictive tools (RISK OF DERM, BEAT)

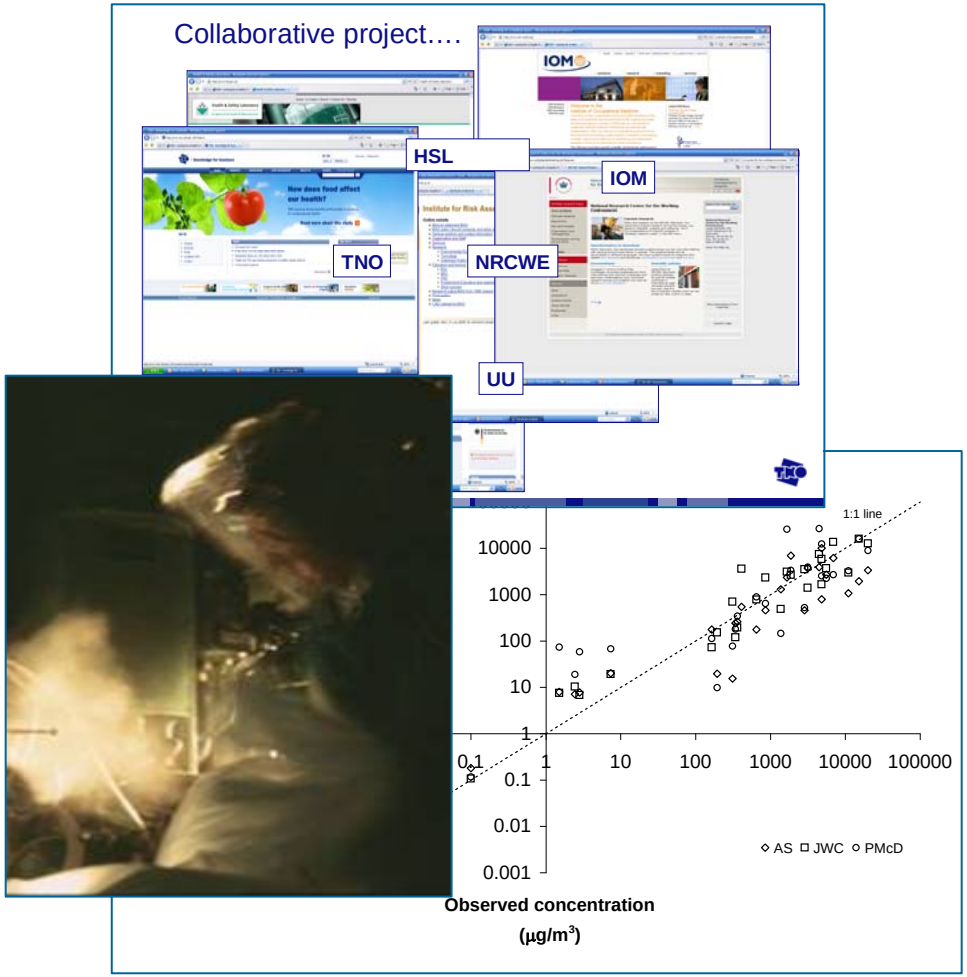
"... there is no scientific method of measuring the results of the body's exposure to risks through dermal contact. Consequently no dermal exposure standards have been set." [Occupational skin diseases and dermal exposure in the European Union (EU-25): policy and practice overview, EASHW, 2008].

# Conclusion: DNEL and OELs

- **IOELVs**
  - Based on EU minimum directives
  - Derived via concensus expert judgement (SCOEL summary docment)
  - Decided by the Commission
  - To be implemented at national level
  - Qualitative instructions how to derive OEL, case-by-case use of AF
- **National OELs**
  - Based on different national legislations
  - Some are derived via concensus expert judgement (e.g. MAK, Sweden)
  - Decided by national government or authority
  - Used to check that employers comply with legislation and healthy work environment
  - Some use AFs
- **DNELs**
  - Based on REACH legislation
  - Derived by importer/manufacturer
  - Used for comparison with exposure scenarios
  - Detailed ”semi-quantitative” instructions how to derive DNEL, including choice of AF
  - Several DNELs may be derived for same chemical

# Exposure Modelling

- Manufacturers must **predict the exposure levels** for downstream users
- Tier 1 (simple) models available are **highly precautionary**
- No validated higher tier models for general occupational hygiene
- **Advanced REACH Tool (ART)** under development by a consortium of European research institutes

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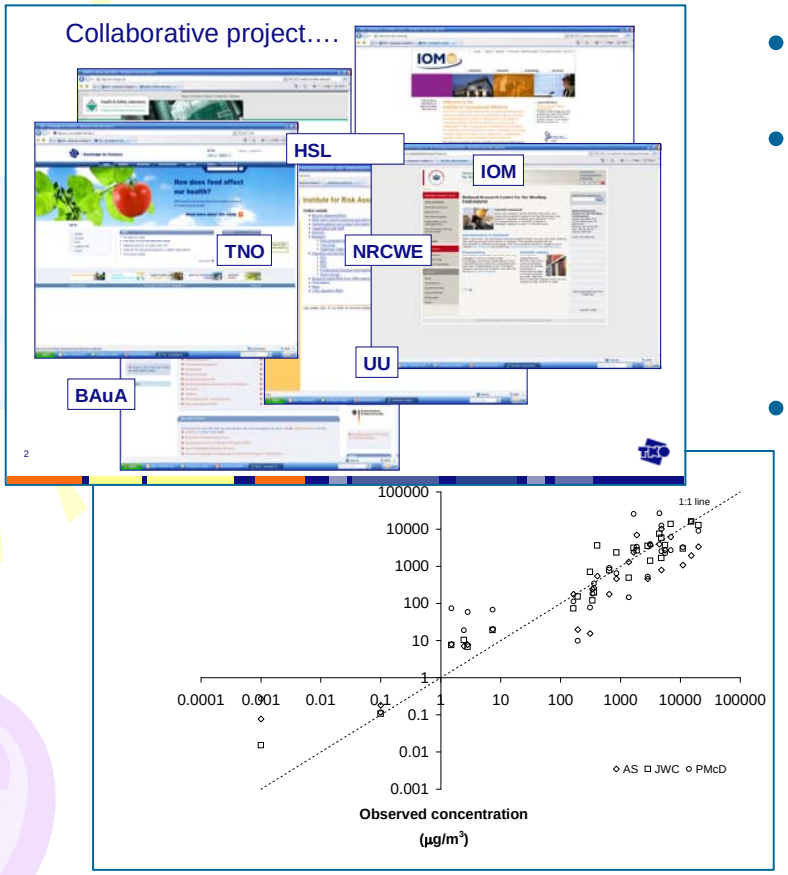
# ECETOC-TRA

- The worker part of the TRA is now available as both an integrated tool (with consumer exposures and the environment) and as a ‘standalone’ version
  - **Excel-based**
  - **For download from the ECETOC website (http://www.ecetoc.org)**

Ref. C.Money/D.Noij, TRA task force

# Advanced REACH Tool (ART)




- Encouraging results in trials
- BOHS is supporting ART
  - Data collation for calibration
  - Expertise on RMMs
- Opportunities for the future
  - Predictions for new plant/processes
  - Better targeting of monitoring strategies

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# Exposure Scenarios

- Describes
  - ✓ processes and tasks
  - ✓ frequency and duration
  - ✓ operational conditions
  - ✓ measured exposure data or modelling data
  - ✓ risk management measures required
- Covers manufacture and intended uses throughout substance life cycle, including waste disposal/recycling
- For each human population exposed (as workers, consumers, indirectly via the environment, or a combination)

*Some questions…*

- *How does the ES fit with a COSHH risk assessment? What if the conclusions are different?*
- *What if my use isn't covered by an ES?*
- *How can a supplier estimate the exposure levels at my site?*
- *Should ES be generic or specific?*
- *Can COSHH Essentials help?*

# Role of Exposure Scenarios

- Exposure scenarios have multiple functions in the REACH system
  - ✓ document Manufacturer's own exposures
  - ✓ provide information to be fed into exposure assessment tools (to enable comparisons with DNELs)
  - ✓ form part of Chemical Safety Report to be submitted with the Registration package to the authorities
- Included as an appendix to **extended Safety Data Sheet**
  - ✓ guidance on how to safely use the substance, for formulators, trade and industrial end users
- Development of ES envisaged as an iterative process of communications between manufacturer and downstream user. Ongoing debate over level of detail a manufacturer should include - generic or specific?

➢ it is a challenge to achieve all these aims in one system

# Generic Exposure Scenarios

## Example of GES titles for Solvents

*From the perspective of how REACH ESs need to be communicated*

- Manufacture of solvents (industrial)
- Bulk loading and repacking of solvents (industrial)
- Formulation & packing of solvent-based mixtures (industrial)
- Coatings (industrial, professional and consumer)
- Cleaning agents (industrial, professional and consumer)
- Drilling muds (industrial)

* List is illustrative and is to be fully develope

## 3b. Justifying the Content of the ES

| Table 1: Mapping Uses in th | Table 2: Characterising the Risks - example Tier 1 sc | | | | | DNEL >100 ppm | |
|---|---|---|---|---|---|---|---|
| Sector/User Group | Process Category / TRA equivalent | Tier 1 assumptions and adjustments where required | | Predicted Exposure - ECETOC TRA estimate | | RMMs for communication - Consolidate into GES or e-SDS (Black text REACH advised; Blue text recommended) | RMM Codes for communication (Black text REACH advised; Blue text recommended) |
| | | OCs (red text Tier 1 adjustments) | RMMs (red text additional Tier 1 adjustments) | Moderate Volatility (ppm) | Significant Dermal exposure? | | |
| Cleaning agents | | | | | | | |
| Industrial (SU3) | PROC1 / TRA1 Closed process (no | >4 hours, ambient temp. | Closed process. No exp | 0.01 | No | Skin and eye protection | PPE16 |
| Industrial (SU3) | PROC8 / TRA7 Discharging to/from vessels | > 4 hours daily; ambient temp. | No LEV | | | | |
| Industrial (SU3) | PROC7 / TRA6 Spray application with LEV | > 4 hours daily; ambient temp. | With LE | | | | |
| Industrial (SU3) | PROC13 / TRA11 Treatment by dipping/pouring | > 4 hours daily; ambient temp. | With LE | | | | |
| Industrial (SU3) | PROC10 / TRA9 Roller application | > 4 hours daily; ambient temp. | No LEV | | | | |
| Professional (SU22) | PROC8 / TRA7 Discharging to/from small | > 4 hours daily; ambient temp. | No LEV | | | | |
| Professional (SU22) | PROC11 / TRA6 Spraying without | > 4 hours daily; ambient temp. | No LEV | | | | |
| Professional (SU22) | PROC13 / TRA11 Treatment by dipping/pouring | > 4 hours daily; ambient temp. | No LEV | | | | |

## Generic Exposure Scenario (Professional Use of Coatings)

**Risk management measures**

Human health

- *Pouring from small containers* : undertake in a well-ventilated area. Wear suitable gloves (type EN374, code FJ) if skin contact likely.
- *Spraying* : carry out in a vented spray booth. I[illegible]o dedicated facility available, then use a respirator conform[illegible]o EN140 (with Type A filter) or better standard and u[illegible] well-ventilated area segregated away from o[illegible] activities.
- *Manual applications* e.g. brushing, rolling, s[illegible] undertake in well-ventilated workplace. Use[illegible] brushes and rol[illegible]here possible. Wear glo[illegible] EN374, code[illegible]act with c[illegible]
- *Equipment cl*[illegible]es (type EN374, code FJ) if prolonged [illegible]nsfer wash-downs in sealed containers. U[illegible]olvent or send for disposal or recycle.

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GES communicates the consolidated RMMs and OCs for the relevant PROCs in an area of application

RMMs and OCs relevant for a task (PROC) clearly distinguished and described in manner relevant for DU

GES format provides the opportunity for the communication of sector product stewardship advice

*** Acknowledgments CEFIC**

# ECHA CSR Tool Chesar

- Supports
  - ✓ exposure scenario building using simple exposure estimation tools (ECETOC-TRA)
  - ✓ reporting of exposure scenarios built with other exposure assessment tools, or based on measured data or libraries
- Flexibility to incorporate more advanced models for exposure estimation and support further development
- First limited version of the tool **due at end 2009 / early 2010,** better version expected mid-2010
- Will not cover
  - ✓ mapping of uses and conditions of use.
  - ✓ organising the communication within the supply chain

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# Issues with CSA/CSR/ES

- Probably the most underestimated part of REACH
- ECHA plans updated guidance
- Supporting industry activities
  - ✓ Generic Exposure Scenarios produced by some trade associations
  - ✓ guidance on developing Specific Exposure Scenarios
  - ✓ libraries of Exposure Scenarios and Risk Management Measures
- Technical issues for industry
  - ✓ exposure standard setting
  - ✓ quantitative exposure prediction
  - ✓ efficiency of Risk Management Measures

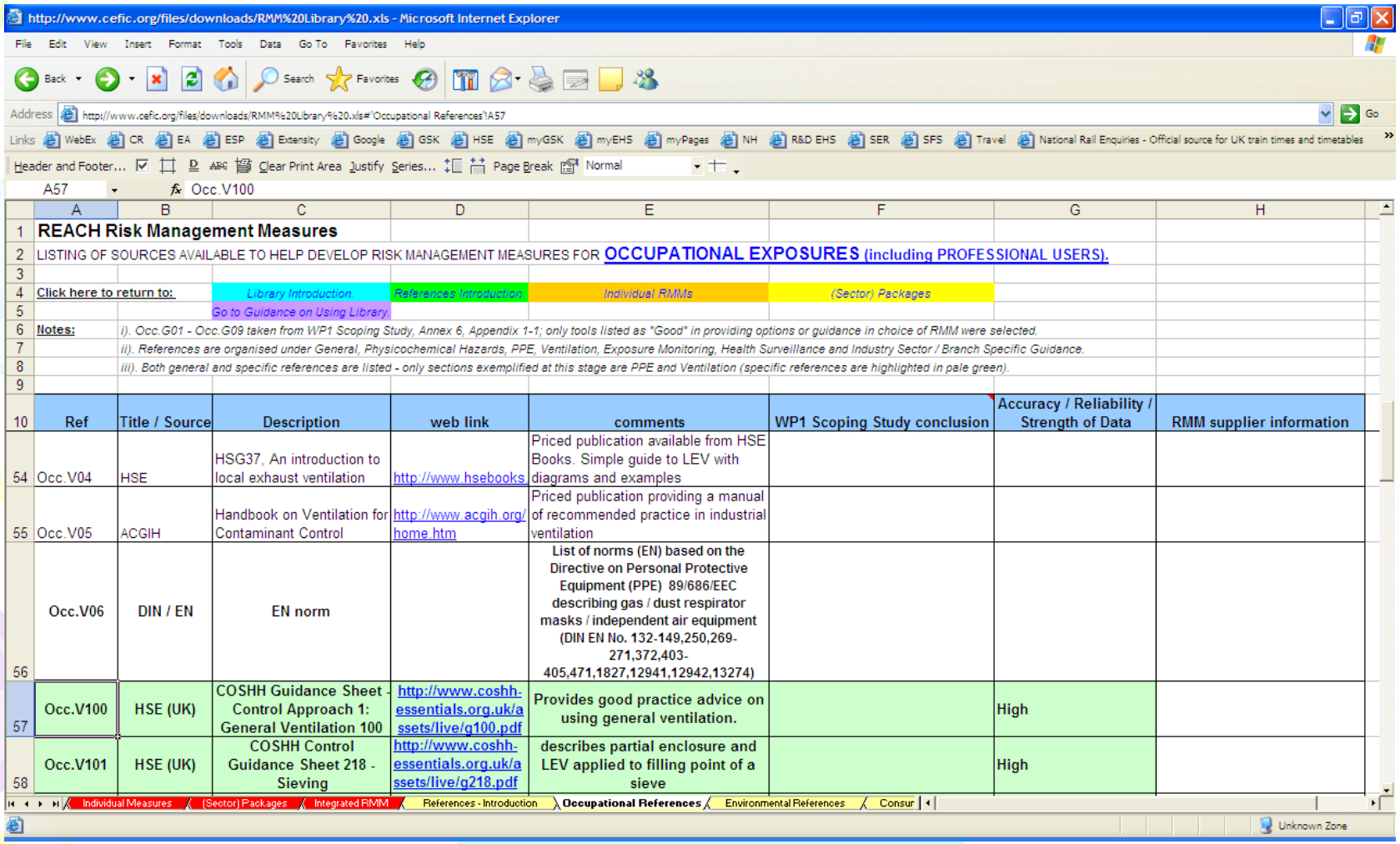
# Risk Management Measures

- Must cover workers, consumers, and general public
- For workers, consider…
  - ✓ Hierarchy of control
  - ✓ Principles of Good Control Practice (COSHH)
  - ✓ All routes of exposure (inhalation, dermal, accidental ingestion)
- Determine residual risk (after RMM implemented)
- **Risk Characterisation** – compare exposure with the relevant DNEL

*Some questions…*

- *How effective are RMM? Do I need to measure exposure?*
- *A different mix of control options may achieve the same result; are both options valid?*
- *Do I have to use the recommended RMM from my supplier?*
- *What if different suppliers give conflicting recommendations?*
- *Will control banding schemes like COSHH Essentials help?*

# CEFIC RMM Library



http://www.cefic.org/files/downloads/RMM%20Library%20.xls - Microsoft Internet Explorer

File Edit View Insert Format Tools Data Go To Favorites Help

Address http://www.cefic.org/files/downloads/RMM%20Library%20.xls#'Occupational References'!A57

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**REACH Risk Management Measures**

LISTING OF SOURCES AVAILABLE TO HELP DEVELOP RISK MANAGEMENT MEASURES FOR **OCCUPATIONAL EXPOSURES** (including PROFESSIONAL USERS).

Click here to return to: | Library Introduction | References Introduction | Individual RMMs | (Sector) Packages

Go to Guidance on Using Library

**Notes:**

i). Occ.G01 - Occ.G09 taken from WP1 Scoping Study, Annex 6, Appendix 1-1; only tools listed as "Good" in providing options or guidance in choice of RMM were selected.

ii). References are organised under General, Physicochemical Hazards, PPE, Ventilation, Exposure Monitoring, Health Surveillance and Industry Sector / Branch Specific Guidance.

iii). Both general and specific references are listed - only sections exemplified at this stage are PPE and Ventilation (specific references are highlighted in pale green).

| Ref | Title / Source | Description | web link | comments | WP1 Scoping Study conclusion | Accuracy / Reliability / Strength of Data | RMM supplier information |
|---|---|---|---|---|---|---|---|
| Occ.V04 | HSE | HSG37, An introduction to local exhaust ventilation | http://www.hsebooks | Priced publication available from HSE Books. Simple guide to LEV with diagrams and examples | | | |
| Occ.V05 | ACGIH | Handbook on Ventilation for Contaminant Control | http://www.acgih.org/home.htm | Priced publication providing a manual of recommended practice in industrial ventilation | | | |
| Occ.V06 | DIN / EN | EN norm | | List of norms (EN) based on the Directive on Personal Protective Equipment (PPE) 89/686/EEC describing gas / dust respirator masks / independent air equipment (DIN EN No. 132-149,250,269-271,372,403-405,471,1827,12941,12942,13274) | | | |
| Occ.V100 | HSE (UK) | COSHH Guidance Sheet - Control Approach 1: General Ventilation 100 | http://www.coshh-essentials.org.uk/assets/live/g100.pdf | Provides good practice advice on using general ventilation. | | High | |
| Occ.V101 | HSE (UK) | COSHH Control Guidance Sheet 218 - Sieving | http://www.coshh-essentials.org.uk/assets/live/g218.pdf | describes partial enclosure and LEV applied to filling point of a sieve | | High | |

Individual Measures | (Sector) Packages | Integrated RMM | References - Introduction | Occupational References | Environmental References | Consur

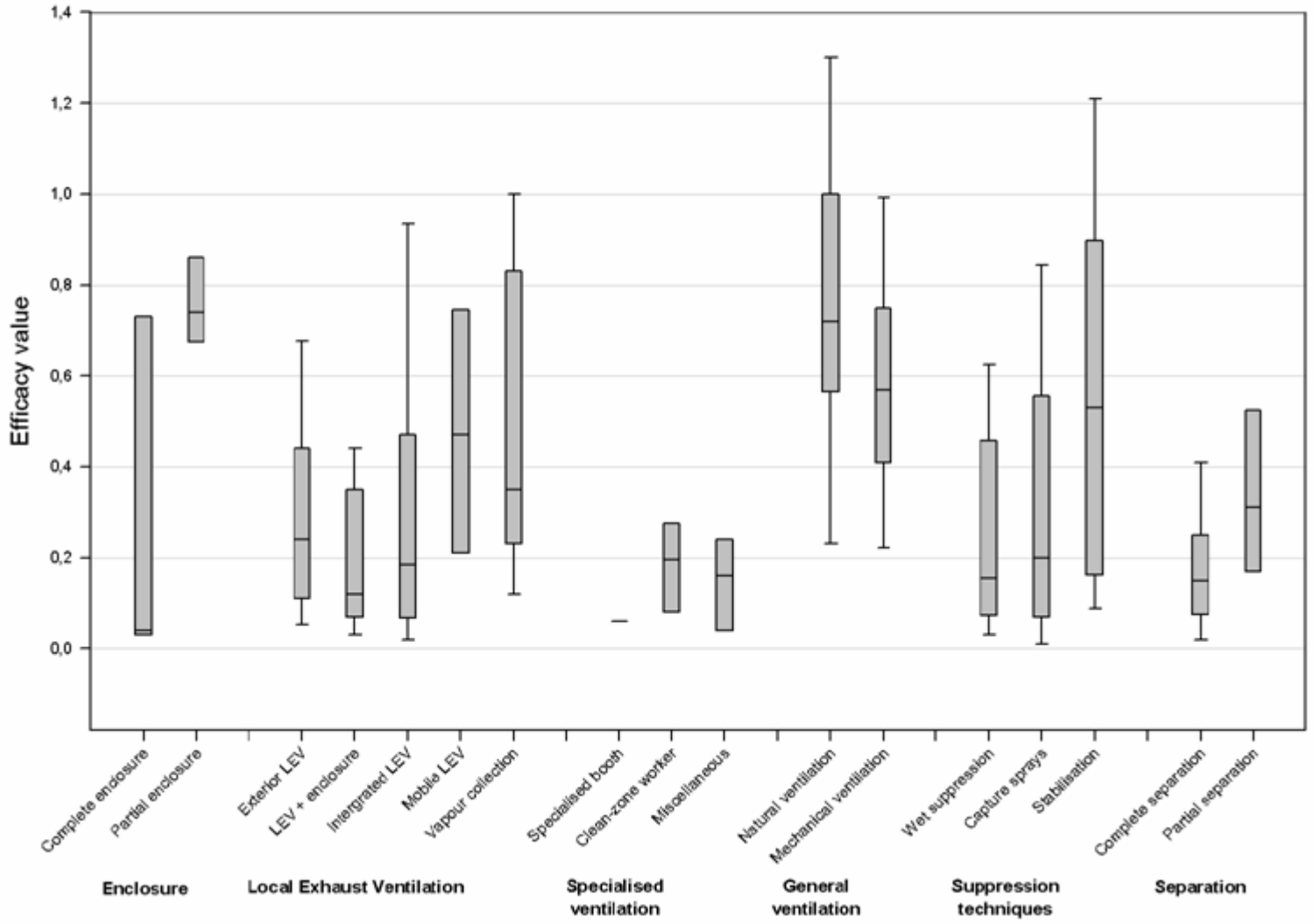
Unknown Zone

# RMM efficiency

- Default and “max. achievable” values for RMM efficiencies in RMM Library
- Evidence base is poor for worker, environment and consumer control measures
- CEFIC RMM task force working with national associations to produce consensus
- Separate initiatives from industry, academia, professions (e.g. ECEL database)

# ECEL-database

## Fransman et al. Ann Occup Hyg, 2008



# Expert review

- Panel of experienced hygienists from BOHS
- Systematic review of ECEL classifications
- Consensus building on efficacy values

# REACH and COSHH interface: DU perspective

## COSHH

- Employers conduct risk assessments and decide control measures of their own operations
- Controls are proportional to risk
  - employers must do what is (reasonably) practicable

## REACH

- Manufacturer/importer responsible for safe downstream use and disposal
- Driven by strong Precautionary Principle rather than risk management

# The Commission view

- OSH legislation (e.g. CAD) is based on principles of minimum requirements Directives transposed into national legislation by each MS.
- REACH is a Regulation with “direct effect”
- Advisory Committee on Safety & Health at the workplace (ACSH) is developing guidance that will set out how employers can meet their obligations under both OSH legislation and REACH - a step by step approach to compliance.
- REACH should improve worker health and safety by providing better information, by establishing new channels of communication between employers and suppliers and by removing more hazardous chemicals from the market.
- Need to comply with the requirements of both sets of legislation - OSH and REACH.

# REACH vs. Workplace Regulation

- *"Dutyholders are...under an obligation to comply with the recommendations in SDSs and CSAs etc."* UK Health and Safety Executive, 2008
- *"a site-specific COSHH assessment, properly informed by the hazard information in the REACH assessment, will take specific workplace conditions into account and should provide the most appropriate recommendations for achieving adequate control of exposure."* BOHS, 2009

# REACH and Occupational Hygiene

- Occupational hygiene is fundamental to successful implementation of REACH
- The challenge for hygienists is
  - ✓ to achieve real improvements in occupational health
  - ✓ to avoid being over-precautionary

**It will be critical to the success of REACH that hygienists can relate their recommendations to solid science and evidence of real health risk**

# Thank-you for listening

# Questions?

Andy Gillies
Gillies Associates Limited
Andy@gilliesassociates.co.uk