Break out group on Guidance update: Occupational Exposure

ENES 7

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R14 update: motivation

- Occupational exposure assessment in CSRs often fail to generate realistic and relevant **risk management measures** for communication downstream

- Some of the advice on **exposure estimation** is no longer current

- CSRs prepared for applications for **Authorisation** have some special considerations that are currently not addressed at all in the guidance

This breakout session is an opportunity to explore some of the key issues for discussion at early stage

Risk Management Measures

- Integrate relevant information on OCs/RMMs from R13.

R13 contents

Risk Management Measures

- Integrate relevant information on OCs/RMMs from R13

- Improve guidance on how to provide realistic and relevant risk management advice. Changes being considered include:
  - Highlight importance of RMMs as part of exposure assessment
  - Introduce concept of worker *exposure assessment input* that is under development and link to use maps
  - Increase emphasis on hierarchy of controls
  - Reduce emphasis on precise measure of effectiveness (e.g. 92%) and increase consideration of controls within effectiveness bands
  - Highlight need to ensure RMMs identified from quantitative assessment are consistent with measures necessary to address all classified hazards (including those without threshold)
  - Clarify what is meant by industrial and professional setting

Exposure Estimation – measured data

- Changes being considered include:
  - Limit guidance to general principles. Remove specific advice on numbers as it is case specific. Refer instead to international standards and guidance

Table R.14-2: Indicative number of measurements needed to determine confidently that the true RCR is below 1

		RCR : <1 - 0.5	RCR : <0.5 - 0.1	RCR : <0.1
		N	N	N
Variation and uncertainty in the data$	Low^	~20-30	12-20	6-12
	Moderate +	~30-50	~20-30	12-20
	High*	>50	~30-50	~20-30

N= number of samples

- Differentiate between approaches for own site assessment and downstream uses
- Provide worked examples elsewhere

Exposure Estimation – exposure models

- Current guidance describes modelling tools in detail(22 pages)
    - Reduce the amount of detail as the information is available on websites
    - Limit description to overview, applicability domain and characterising inputs and outputs
    - Update the information provided

- Agree and give guidance on issues relating to modelling tools. These include:
    - Use of PROCs 1, 2 & 3 (closed processes) –these are limited to chemical industry
    - professional and industrial "use" (setting)– when should they be applied
    - How to improve link between input for worker exposure assessment and existing generic exposure scenarios/control sheets/other information available from OSH

Exposure Estimation – rating criteria

- Re-evaluate criteria currently provided, including increasing confidence in modelled data (currently rated as medium to low quality data, with acceptable confidence)

Table R.14-1: Workplace exposure assessment rating criteria

Data characteristics	Comments & interpretation
High quality data **Actual measurement data** of high quality, e.g. personal exposure data (including that obtained by biological monitoring) that are representative of the scenario being described; which have been collected and analysed according to recognised (e.g. CEN or equivalent) protocols; and that are available as sets of raw data supported by information on key exposure determinants.	This form of data is likely to enable a decision on whether or not there is safe use. There may be a need for more information, if key activities in the exposure scenario are not covered by measurement data presented. Data confidence is high.
Medium quality data **Analogous measurement data** of a similar quality to the above and which describe exposures that derive from: • other substances having similar exposure	This form of data is likely to enable a decision whether or not the use is safe. A conclusion that there is a need for more information may be appropriate when the

Exposure Estimation – acute exposures

- Current guidance is based on acute exposure measurements. Agree?
  - N = 20 and 95th percentile

- Current guidance for extrapolation from full shift estimates (measured or modelled). Agree?
  - Gives 8 multiplying factors to extrapolate from full shift to acute (15min)
  - Factor is 2 for 90th percentile full shift to 95th percentile acute

Table R.14-3: Multiplying factors to generate acute reasonable worst-case value from full shift values

(Based on calculations using equations from Kumagai and Matsunaga (1994))

Situation	Full shift reasonable worst case = 75th percentile		Full shift reasonable worst case = 90th percentile	
Acute (15 minute average estimator	95th percentile	99th percentile	95th percentile	99th percentile
Not very high variability (default)[a]	4	20	2	6
Very high variability[b]	6	40	1.5	10

- Clarify observed incorrect use of 15 min exposure time to represent acute exposure with Ecetoc TRA

Exposure Estimation – dermal exposures

- Strengthen role of qualitative assessment in identifying risk management measures for dermal exposure

- Address situations where quantitative assessment results in over-estimate due to limitations in exposure models, and consequently overly precautionary risk management measures

- Address need to provide protection for all body parts potentially exposed

- Reduce emphasis on PPE, with increased focus on engineering / management controls

- Consider if closed conditions (such as inline sampling systems, closed & automated processes) can be deemed to give rise to zero exposure

Exposure Assessment as part of Application for Authorisation

Proposed additional section outlining elements to consider

- Exposure estimate expected to draw on measured data (biomonitoring, inhalation exposure etc.)
- OC/RMMs to be based on actual conditions
- Risk characterisation against DNEL(threshold) or dose response curves (non threshold)
- Assessment to include impact assessment

Additional Points

- Issues from your experience using R14
- Other issues to consider

First Draft
Q1 2015

PEG
Q2 2015

Publication
Q1 2016
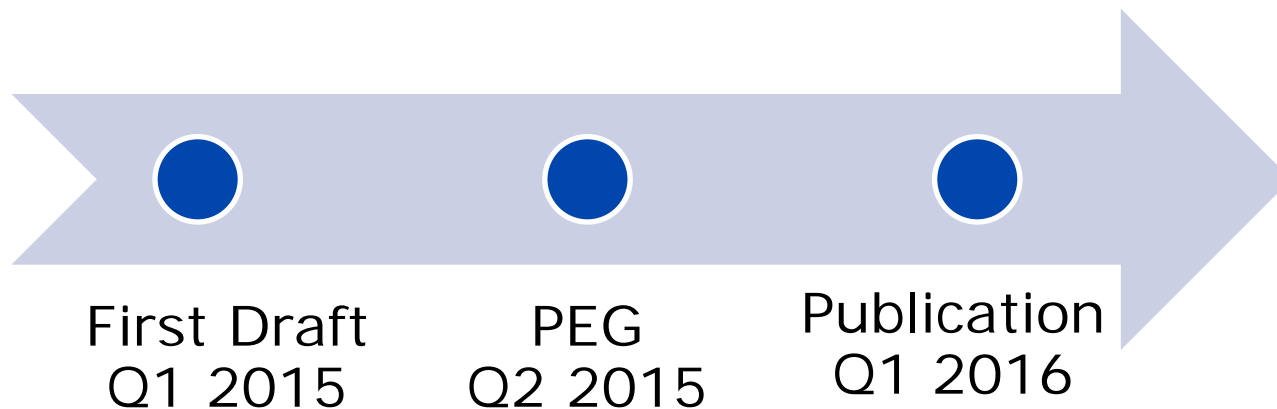
Overview of Key Discussion Points

- Risk management measures
    - Incorporate elements from R13
    - Introduce worker exposure assessment input approach
    - Strengthen link to existing OSH controls/hierarchy/banding etc.
    - Clarify aspects such as closed/open, industrial/professional

- Exposure estimation
    - Reduce details on measurement data but if feasible, provide examples elsewhere (requires input)
    - Reduce details on modelling tools
    - Modify rating criteria
    - Clarify acute exposure assessment
    - Expand advice on dermal exposure

- CSA in application for authorisation

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