Break out group on Guidance update: Consumer Exposure

ENES 7

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Recap on current Guidance

- General exposure considerations (15.2)
  - Scope (e.g. includes articles or post use exposure)
  - Reasonable worst case situations
  - Routes of exposure
  - Phases of activity
  - Acute versus chronic
  - Combined uptake via different routed
  - Compilation OC and RMM (focus on product integrated RMM)
- Calculation of exposure (15.3)
  - Basic Tier 1 equations for the three routes with examples; differentiation between mixtures and articles
  - Exposure to non-volatile substances
- ECETOC TRA consumer Tool (detailed description)(15.4)
- ConsExpo (summary description) (15.5)

Recap on current Guidance

- Advanced refinements of Tier 1 tool and higher Tier assessment (15.6)
  - For TRA consumer
  - For consexpo
  - Measurements
- Risk Characterisation (15.7)
- References (15.8)
- Appendices
  - Consumer product and article categories
  - Compatibility of Tier 1 algorithms with TRA
  - Valuable sources of release and exposure data
  - Other computer tools
  - Exposure factors (anthropometric, housing, ….)

Motivation and scope of update

- Industry initiative to build assessment input data sets
  - Current Tier 1 tools are very conservative (difficult to demonstrate control od risk).
    - Crude model based on Tier equations (e.g. TRA)
    - Default values for exposure determinants do not match reality
  - Development of SCEDs by industry as a sector driven refinement strategy
- Clarification regarding assessment of occasional/rare uses
- Update of information on modelling tools and measured release from products
- Integrate aspects from R.17 and R.13 and other readability issues
- Move Tier 1 equations an Appendix and remove details on TRA tool

New chapter on SCEDs

- Product Specific Datasets suitable to be fed directly into the TRA to refine the exposure assessment; to be developed at DU sector level
- Refinement of default values to be explained and references to the source of information
- Exposure determinants in the SCED format
  - SCED characteristics (identifier, scope)
  - User characteristics (adult/child)
  - Common Parameters
    - Concentration in mixture
    - Frequency over a day
    - Frequency over a year
  - Route specific parameters

Inhalation parameters

- Relevance of route
- Amount of product per application
- Spray application (yes/no)
- Exposure time per event
- Inhalation transfer factor (> 0-1):
  - Adjusted fraction of product amount available for release to air under the use-specific conditions.

Dermal parameters

- Relevance of route
- Skin contact area
- Dermal transfer factor (> 0 -1)
  - Adjusted loading to skin (resulting from smaller exposed skin area and/or thinner product layer in contact)

Oral parameters

- Relevance of route
- Oral intake
  - Ingestion from hand to mouth contact or
  - Ingestion via sucking (mouth contact area) from article surface
- Oral transfer factor (> 0 - 1):
  - Adjusted transfer to mouth if only a fraction of the substance contained in the contact layer is transferred.

Assessment of infrequent uses (1)

- Starting point for consumer exposure assessment:
  - Exposure resulting from one application (event exposure)
    - “Short” exposure event (minutes to few hours)
    - Longer exposure time with decreasing air concentration (post application or article use indoor)
  - Daily use (at least once a day)
- Exposure concentration usually assessed against the chronic DNELs (unless substance is classified for acute systemic toxicity)
- Challenge: How to assess exposure/risk for infrequently occurring uses?

Assessment of infrequent uses (2)

- A particular assessment for infrequent uses may be relevant when
  - after refining the estimate for event exposure (based on SCED, higher tier modelling or measured data), the event exposure is higher than the chronic DNEL and
  - no DNEL for acute systemic toxicity available and
  - sufficiently representative evidence is available that a high percentile of consumers use the substance less than e.g. once a week.
- Approach to refine the assessment: Averaging/dilution of exposure over time

Assessment of infrequent uses (3)

Potential Exposure reduction factors

Event	Frequency	Exposure reduction factor against event exposure	
Occasional	< once a week	0.2 (ECETOC)	
Infrequent	< once a month < once in 6 months	0.04 (ECETOC) 0.01 (ECETOC)	

Event	Frequency	Exposure reduction factor against event exposure	
Daily	once a day	Variable depending on duration of exposure within a day	

Exposure estimation models (new)

- Tier I: ECETOC v.3.1 (compared to v.2)
  - Inhalation: basic ventilation/saturated vapour concentration leads to lower air concentration
  - Dermal and oral transfer factor (default = 1)
  - Inhalation transfer factor + frequency over the year
- TIER I (developed by sectors organisation)
  - REACT (AISE), covering PC35, PC3
  - EGRET (ESIG, solvent association); modified TRA
- Tier II: RIVM emission model
  - route specific models (inhalation)
  - Suitable for releases from e.g. construction materials)

Summary

- Inclusion of SCED approach
- Clarification of assessment approach for infrequent uses
- Update on particular models
- Integration of R.13 and R.17 elements (very few)
- Update on reference to measured data
- Move equations and tool description to Appendix
- General update on tools and sources in the appendices