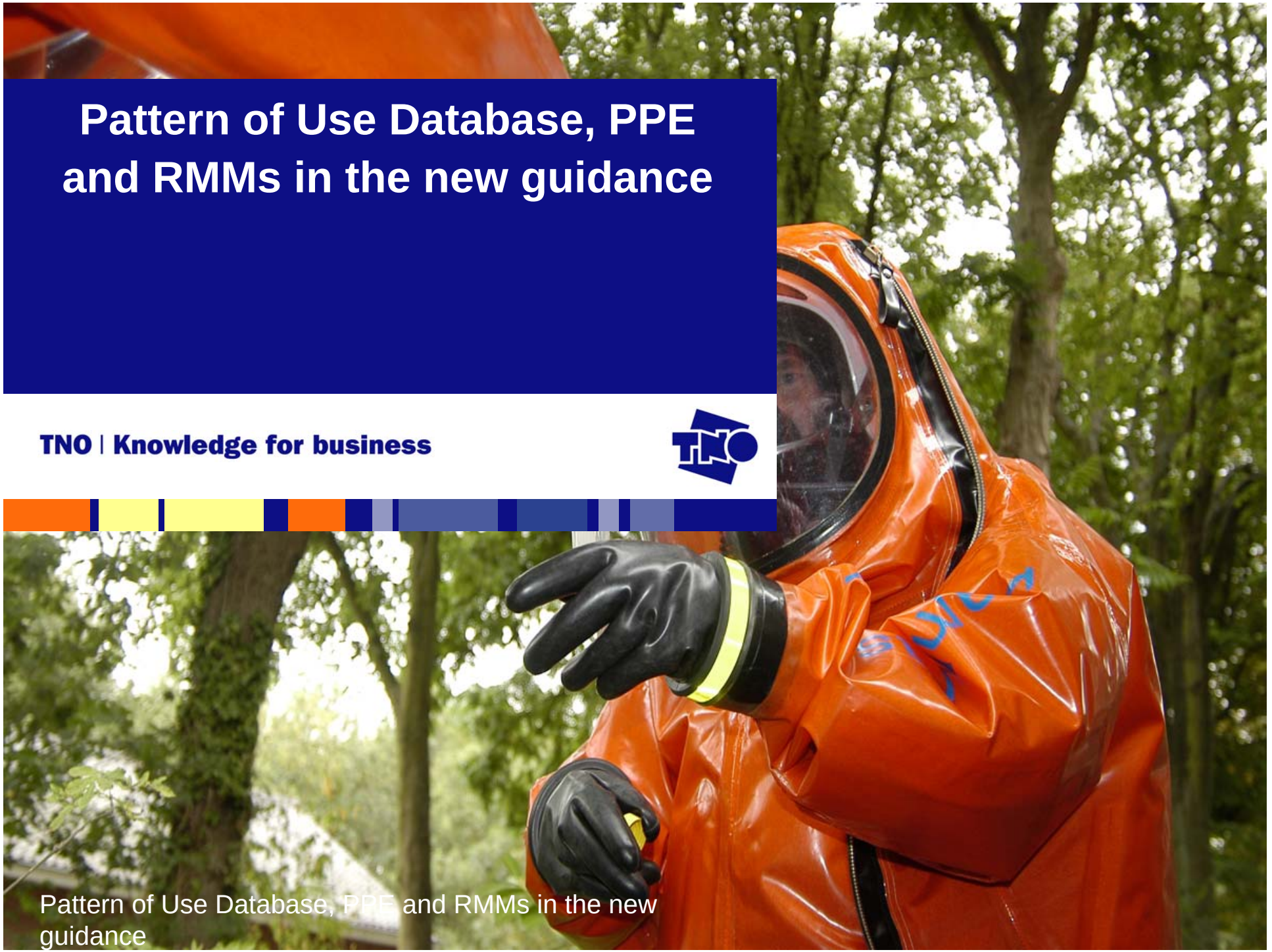
Pattern of Use Database, PPE and RMMs in the new guidance

TNO | Knowledge for business



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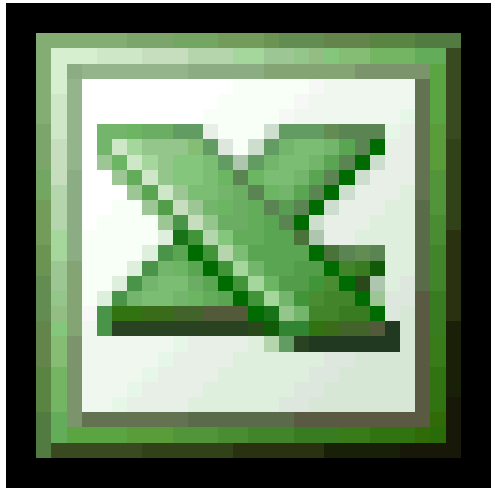
Pattern of Use Database



Background

- 23 product types and all sort of uses → need for generic use patterns
- Frequency and duration important determinants for the level of exposure
- Information on use patterns, duration and frequency often lacking or inconsistent (TNsG 2002)

Purpose

- Establish generic use patterns for all product types
- Defaults for duration and frequency
  - For each product type
  - For different tasks
  - For different formulations
- Limited to professional use
- Reasonable worst case
- 90% coverage

Information source

- Organisations
  - European Biocidal Product Forum (EBPF)
  - Competent Authorities USA (EPA)
  - CA California (Cal-Department of Pesticide Regulation)
  - CA Canada (Health Canada Pesticide Management Regulation Agency)
  - Biocides Taskforce of the American Chemistry Council (ACC)

- Databases
  - Ctgb, NL
  - Pesticide approval System, UK
  - BVL, DE

Information source

- Biocides Information Services (BIS)
  - University of Ulster
  - Telephone interviews with leading companies for all product types

- Literature

Result

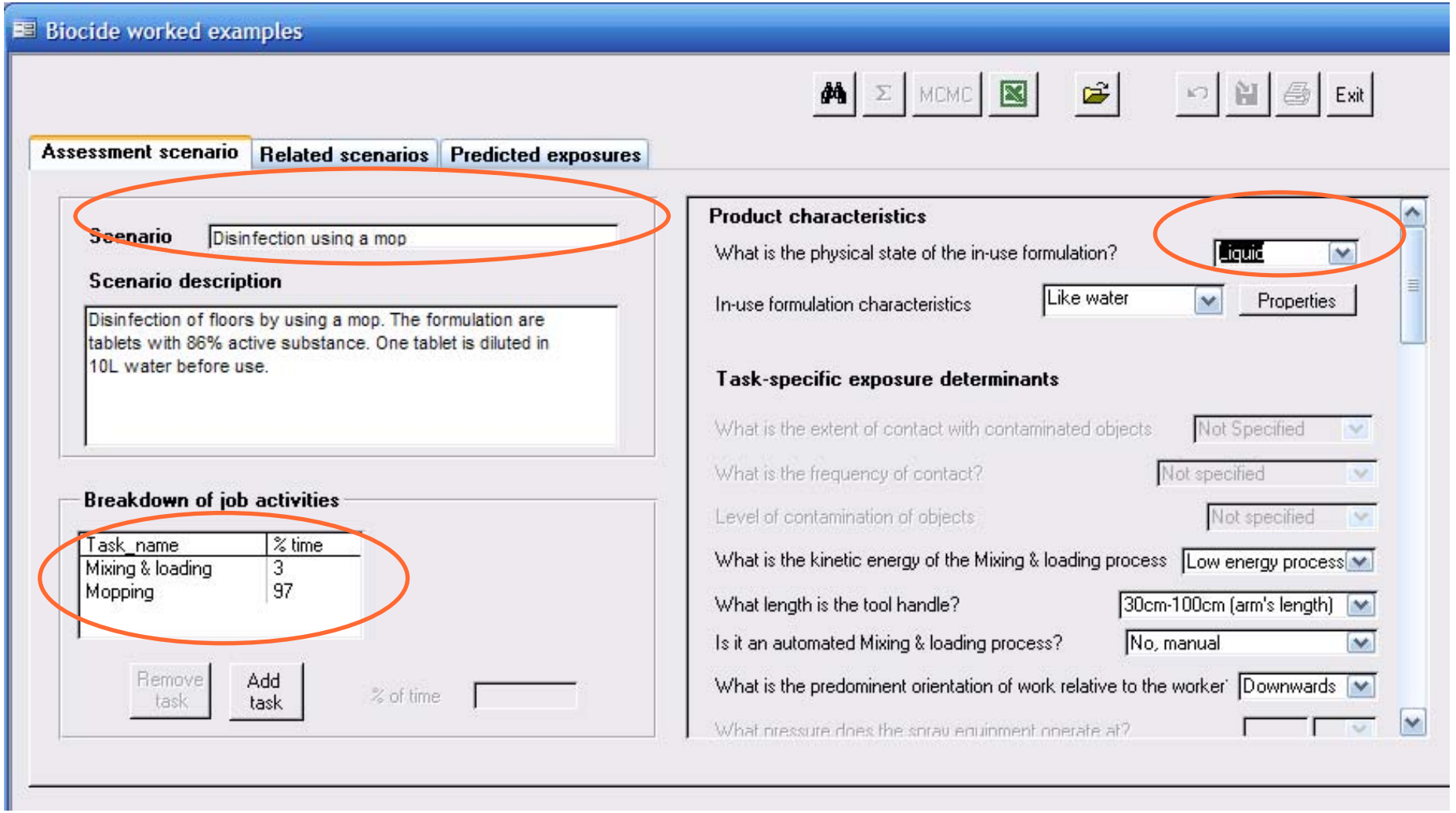
→ draft database

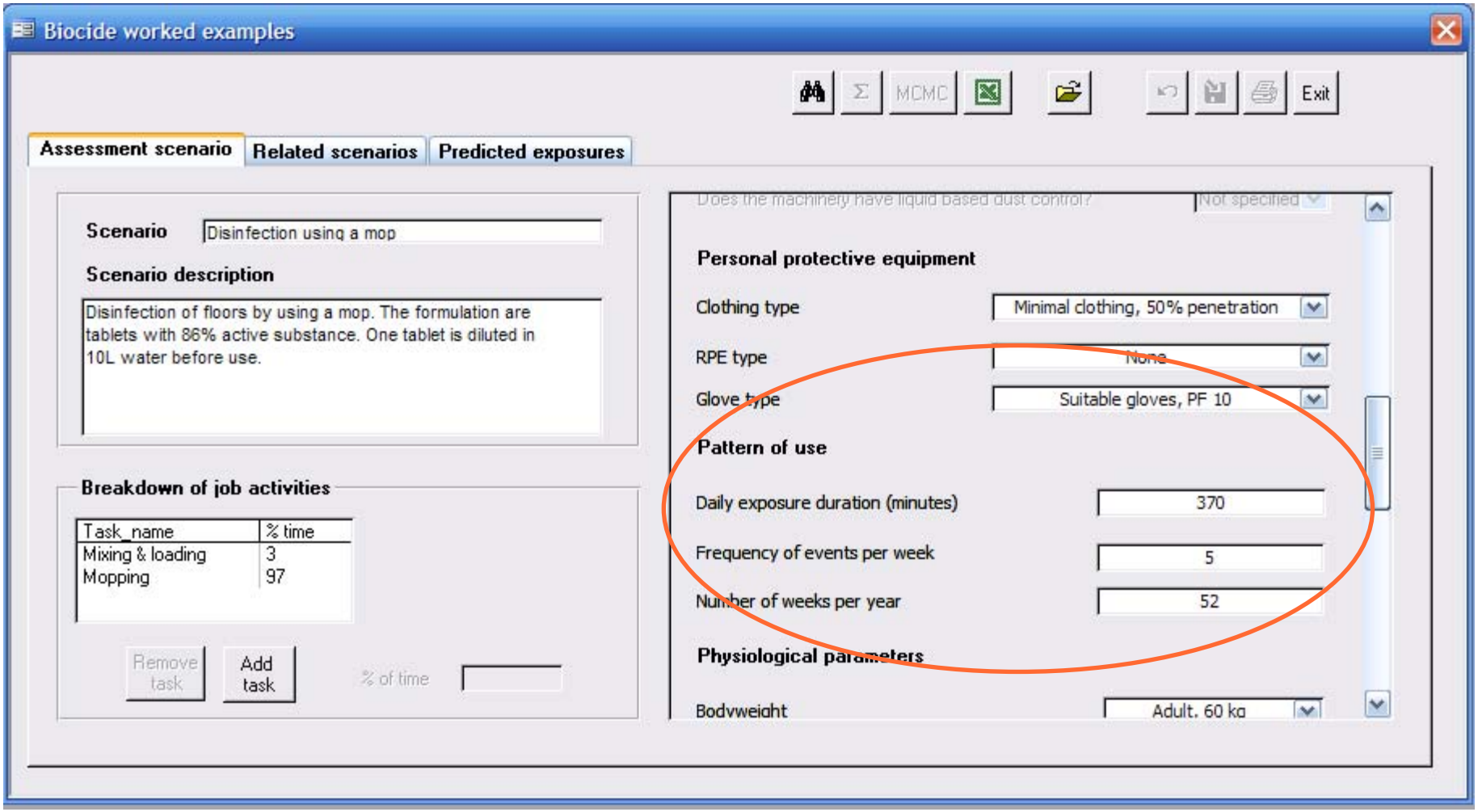
→ industry (through EBPF) to comment on

→ final version

Use Pattern Database

	A	B	C	D	E	F	G	H	I	J
1	**PT 2: Private and public health area disinfectants**									
2	Formulation	If formulation is "other" then define	Mixing and loading phase	Total duration mixing and loading per day (default)	Exposure frequency mixing and loading (default)	Application phase (category)	Description of phase	Total duration application per day (default)	Exposure frequency application (default)	Comments
3	**Liquid**									
4	Liquid		Pour and dilute	10 minutes	Daily	Wiping	Disinfecting surfaces using a cloth	6 hours	Daily	
5	Liquid		Pour and dilute	10 minutes	Daily	Mopping	Disinfecting surfaces using a mop	6 hours	Daily	
6	Liquid		Pour and dilute	10 minutes	Daily	Spraying	Disinfecting surfaces using a hand-held spray to disinfect the sprayed surface	30 minutes	Daily	
7	Liquid		Pour and dilute	10 minutes	Daily	Brushing	Brushing surface	6 hours	Daily	
8	Liquid		Fill undiluted	10 minutes	Daily	Handling	Put dosing system into toilet	1 hour	Daily	
9	Liquid		Pour and dilute	10 minutes	Daily	Scrubbing	Scrubbing surface	1 hour	Daily	
10	Liquid		No mixing and loading required			Other	Decontamination in open unit	1 hour	Daily	
11	Liquid		No mixing and loading required			Other	Decontamination in semi-automated unit	1 hour	Daily	
12	Liquid		No mixing and loading required			Other	Decontamination in automated unit	1 hour	Daily	
13	Liquid		Pour and dilute	10 minutes	Daily	Washing articles	Wash articles in machine (wash machine / dish washer)	1 hour	Daily	
14	Liquid		Fill undiluted			Fogging	Fogging rooms	1 hour	Daily	


Biocide worked examples
MCMC
Exit
Assessment scenario
Related scenarios
Predicted exposures
Scenario
Disinfection using a mop
Scenario description
Disinfection of floors by using a mop. The formulation are tablets with 86% active substance. One tablet is diluted in 10L water before use.
Breakdown of job activities
Task_name
% time
Mixing & loading
3
Mopping
97
Remove task
Add task
% of time
Product characteristics
What is the physical state of the in-use formulation?
Liquid
In-use formulation characteristics
Like water
Properties
Task-specific exposure determinants
What is the extent of contact with contaminated objects
Not Specified
What is the frequency of contact?
Not specified
Level of contamination of objects
Not specified
What is the kinetic energy of the Mixing & loading process
Low energy process
What length is the tool handle?
30cm-100cm (arm's length)
Is it an automated Mixing & loading process?
No, manual
What is the predominent orientation of work relative to the worker
Downwards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% time
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97
Remove task
Add task
% of time
Does the machinery have liquid based dust control?
Not specified
Personal protective equipment
Clothing type
Minimal clothing, 50% penetration
RPE type
None
Glove type
Suitable gloves, PF 10
Pattern of use
Daily exposure duration (minutes)
370
Frequency of events per week
5
Number of weeks per year
52
Physiological parameters
Bodyweight
Adult, 60 kg

Remarks

- When more detailed information for the product is available → justification of other data to use
- 10% that's not covered → registrant should provide justified information
- Regional differences
- Climatic differences
- CA need to ensure relevance of a stated pattern of use!

Personal Protective Equipment

Definition

- Personal Protective Equipment (PPE): *all equipment (including clothing affording protection against the weather) which is intended to be worn or held by a person and which protects them against one or more risks to their health and safety*

Background

- Current knowledge for estimating reduction factors through the wearing of adequate PPE/RPE is incomplete
- Agreeing terms “appropriate” and “adequate” long way off
- Need for harmonised approach in the registration process of biocides

Purpose

- To achieve a consistent and transparent approach for the selection of protection factors for PPE and RPE

Information source

- Gerritsen-Ebben MG, Brouwer DH, and Hemmen van JJ , Effective Personal Protective Equipment (PPE): Default setting of PPE for registration purposes of agrochemical and biocidal pesticides, TNO Report V7333 (2007).
- Gerritsen-Ebben, M.G.; Brouwer, D.H.; Hemmen, J.J. van., 2007. Personal protective equipment for registration purposes of pesticides, Communications in Agricultural and Applied Biological Sciences 72 (2007) 2, p. 87-93.
- Defaults presented in TNsG (old version)

Work done in TNO project

- Project funded by Dutch Ministry of Social Affairs and Employment
- Goal: To achieve an internationally harmonised set of PPE protection factors for regulatory use (discussion paper)
- Literature search
- Current approaches of regulatory authorities in North America (EPA, PMRA, Cal-DPR), Europe (Member States) and Australia
- Industry organisations (EU and USA)
- Academic groups working in this area
- → consultation document
  → commented and reviewed (2×)
  → proposal set of defaults for PPE

Principles behind defaults

- Potential exposure loading taken as true value despite variability and uncertainty in exposure (which is also not yet taken into account in models)

- Skin penetration not considered

- Label compliance
  - Protection afforded in field of relevance (fit for purpose)
  - Ergonomics and thermo physiology issues dealt with before label set up

- Differences between safety performance criteria PPE in standards and tests and actual/normal conditions of use

Defaults inhalation exposure reduction

- Use Assigned Protection Factors (APF) from ANSI, BSI and BGR → Use lowest of both values if they differ
- Overall performance of respiratory protection during actual use has been tested in specifically designed workplace protection studies (valid for 95% of adequately trained and instructed wearers)

Mask type	Filter type	BS 4275	ANSI Z88.2		BGR 190
Filtering half masks	FFP1	4			4
	FFP2	10			10
	FFP3	20	10		30
Half or quarter mask and filter	P1	4			4
	P2	10			10
	Gas	10	10		30
	GasXP3	10	10		30
	P3	20	10		30
Filtering half masks without inhalation valves	FMP1	4			
	FMP2	10			
	FMGasX	10	10		
	FMGasXP3	10			
	FMP3	20	10		
Valved filtering half masks	FFGasXP1	4			
	FFGasX	10	10		
	FFGasXP2	10			
	FFGasXP3	10	10		
Full face masks and filter	P1	4			4
	P2	10			15
	Gas	20	100		400
	GasXP3	20			
	P3	40	100		400
Powered filtering devices incorporating helmets or hoods	TH1 all types	10	100		5
	TH2 all types	20	100		20
	TH3 (semi)hood/ blouse	40	1000		100
Power assisted filtering devices incorporating full, half or quarter masks	TM1 (all types)	10	50 (Half face)	100 (full face)	10
	TM2 (all types)	20	50 (Half face)	100 (full face)	100
	TM3 (half face) particle, gas or combined filters	20	50		
	TM 3 (full face) gas or combined filters	40	1000		500

Defaults dermal exposure reduction

- Determination of Assigned Protection Factors (APF) for protective clothing and gloves is much more complex:
  - Multi-compartment origin of contamination
  - Interference human behaviour
  - Laboratory test data:
    - Penetration
    - Permeation
    - Break through times

Defaults dermal exposure reduction

Descriptor	Default protection factor
Clothing penetration (only for dry substances*) – for a non-professional wearing: long-sleeved shirt and trousers or skirt with shoes; no gloves worn (central tendency)	50% protection
Wearing protective gloves	90% protection
Wearing dry* cotton coveralls	75% protection
Wearing ‘impermeable’ coveralls	95% protection

* Only for dry substances. Dry is introduced here, since wet coveralls will offer no protection, whatsoever.

Example: Gloves

- Considered as barriers of hands and wrists against liquids
- No one glove material is a barrier to all chemicals
- Solvents presents the greatest challenges to barrier effectiveness
- Gloves should be checked for holes/ cracks before putting on
- Gloves should be washed before taking off
- Taking on and off should be done as little as possible

Example: Gloves






Remarks

- Engineering controls have higher priority than PPE (last resort)
- Any protective equipment must be properly designed, fitted, worn and maintained to be effective
- More than one item of PPE → compatible
- Adequate information, instruction, training
- Gloves must provide protection against hands and lower forearms
- Default protection values should only be used after careful consideration of the exposure scenario and the biocidal formulation involved

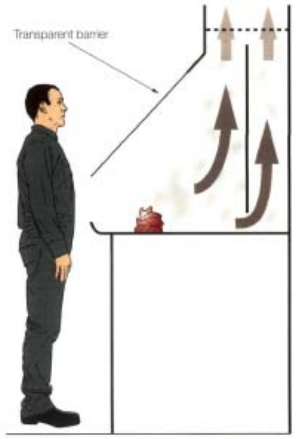
Future developments

- Development of Guidance for Risk Management Measures (RMMs) under REACH
- Further work comparison outer and inner dosimeters and whole body garments → penetration factors (very different)
- Further integration of studies on material/ fabric penetration and/or permeation and field studies with garment attires
- Inter-laboratory studies to determine the effective efficacy under real conditions of use

Future developments

- Studying relation between exposure scenarios, dermal loading and protection by clothing attires (i.e. Safe Use Initiative)
- Biological monitoring or whole body dosimeter studies to focus on woven and nonwoven materials conducted over realistic time periods (operators habits, PPE maintenance, decontamination, durability)
- More solid data to better underpin defaults proposed

Risk Management Measures



Background

- Exposure assessment: exposure to biocide is prevented or controlled
- Prevention: elimination, substitution or modification of process or substance
- For biocides, with myriad of application methods available, preventing exposure is in many cases not practicable
- Exposure must be controlled!

Control options

- Structure related: general ventilation
- Engineering: LEV, containment in pipework
- Technical (especially for consumers): bait boxes, child-resistant fastenings
- Administrative: training and supervison workers, exclusion of residents from treated spaces
- Personal: PPE/RPE

RMM library REACH

RMM Library

- Reference to key publications
- NO EFFICACY DATA!
- → not (yet) suitable for Biocides

New developments

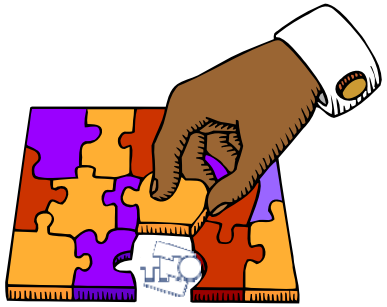
- ECEL (Exposure Control Efficacy Library)
  - Localized controls / containment
  - Based on peer-reviewed literature (90 articles)
  - Efficacy range
  - Expert elicitation necessary (workshop January 2009)
  - Input for ART (Advanced REACH Tool)
  - Concept defaults derived

Reference ECEL

Fransman W., Schinkel J., Meijster, T., van Hemmen J., Tielemans E., Goede H., Development and Evaluation of an Exposure Control Efficacy Library (ECEL). Ann. Occup. Hyg., Vol. 52, No. 7, pp. 567–575, 2008

Q&A

- Thank you for your attention
- Dank voor uw aandacht



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