Exposure & Control Banding Models

Tools for risk prioritization and risk management

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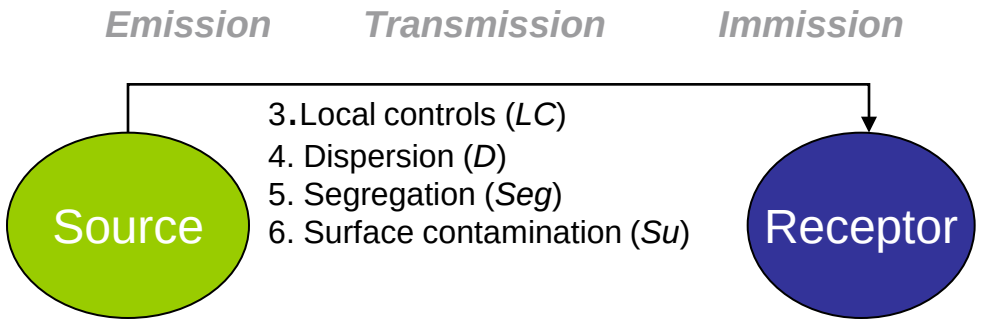
Fate of aerosols or substances



Mass generation rate [g/min]

Mass concentration [mg/m^3]

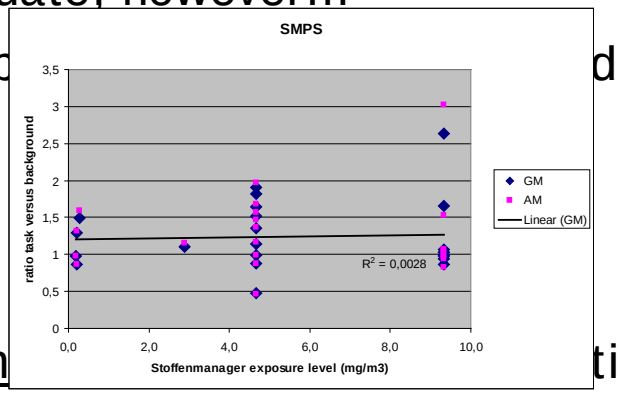
REACH First Tier Inhalation Model

Models suitable for nano?

Ecetoc TRA (W) and Stoffenmanager and NANOSH –NANOINNOV dataset

- Basic concepts of models might be adequate, however…

No correlation could be observed b d particle number concentration**



1)scenarios derived data set were not optim tial resolution of the models could not fully be exploited

2) the categories of the model variables are not scaled to nano-materials / calibrated resulting in loss of power of contrast

3) exposure metric (mass concentration) probably not optimal

coagulation

Emission Transmission Immission

3 Local controls (LC)

Journal of Exposure Science and Environmental Epidemiology (2011), 1–14

www.nature.com/jes

Conceptual model for assessment of inhalation exposure to manufactured nanoparticles

T. SCHNEIDER[a,b], D.H. BROUWER[c], I.K. KOPONEN[b], K.A. JENSEN[b], W. FRANSMAN[c], B. VAN DUUREN-STUURMAN[c], M. VAN TONGEREN[d] AND E. TIELEMANS[c]

Mass generation rate [g/min] *Mass concentration [mg/m³]*

Additional ‘nano features’

Particle size distribution/
number concentration

Particle size distribution/
number concentration
(active) surface area concentration

‘Nano- specific’ Emission generation domains

Source domain	Examples
Fugitive & incidental point source emission during MNM **synthesis**	Leaks through connections, seals etc during MNO synthesis/ incidental release
Release of MNM particles during **handling**/ transfer of MNM **powder**/ bulk material	Bagging/ bag dumping Weighing Dispersion/ compounding in composites
Intermediates master batch/ granules liquid dispersions **Ready-to-use’ products**	 Pouring/ injection moulding Pouring/ stirring/ mixing Nanofilm sprays dispenser Nano coatings
Machining/ abrasion of (solid) MNM-enabled (end) products	Low (abrasion) energy High energy (sanding/ grinding, cutting)

Basics Control Banding Tools

- Qualitative risk assessment in context of uncertainty
- Risk paradigm
  - R= f { (hazard/ severity), (exposure/probability)}

Precautionary principle

- Uncertainties: conservative approach risk: → minimize exposure

Risk/Control Banding

- Hazard (severity) and Exposure (probability) bands linked (not quantitatively) to Risk Bands
- Risk bands linked to Level of Control
  - CL 1 (Ventilation)
  - CL 2 a/b (LEV/ fume hood)
  - CL 3 (Containment)
  - CL 4a/b (Full containment/ review by specialist)

Note: Exposure models include control measures in exposure estimates!

Risk Level Matrix (Example)

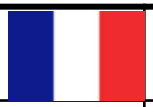
EXPOSURE BANDS \ HAZARD BANDS	A	B	C	D	E
1	3	3	3	2	1
2	3	3	2	2	1
3	3	2	2	1	1
4	2	1	1	1	1

In CB tools are Risk levels associated with recommended Level of Control

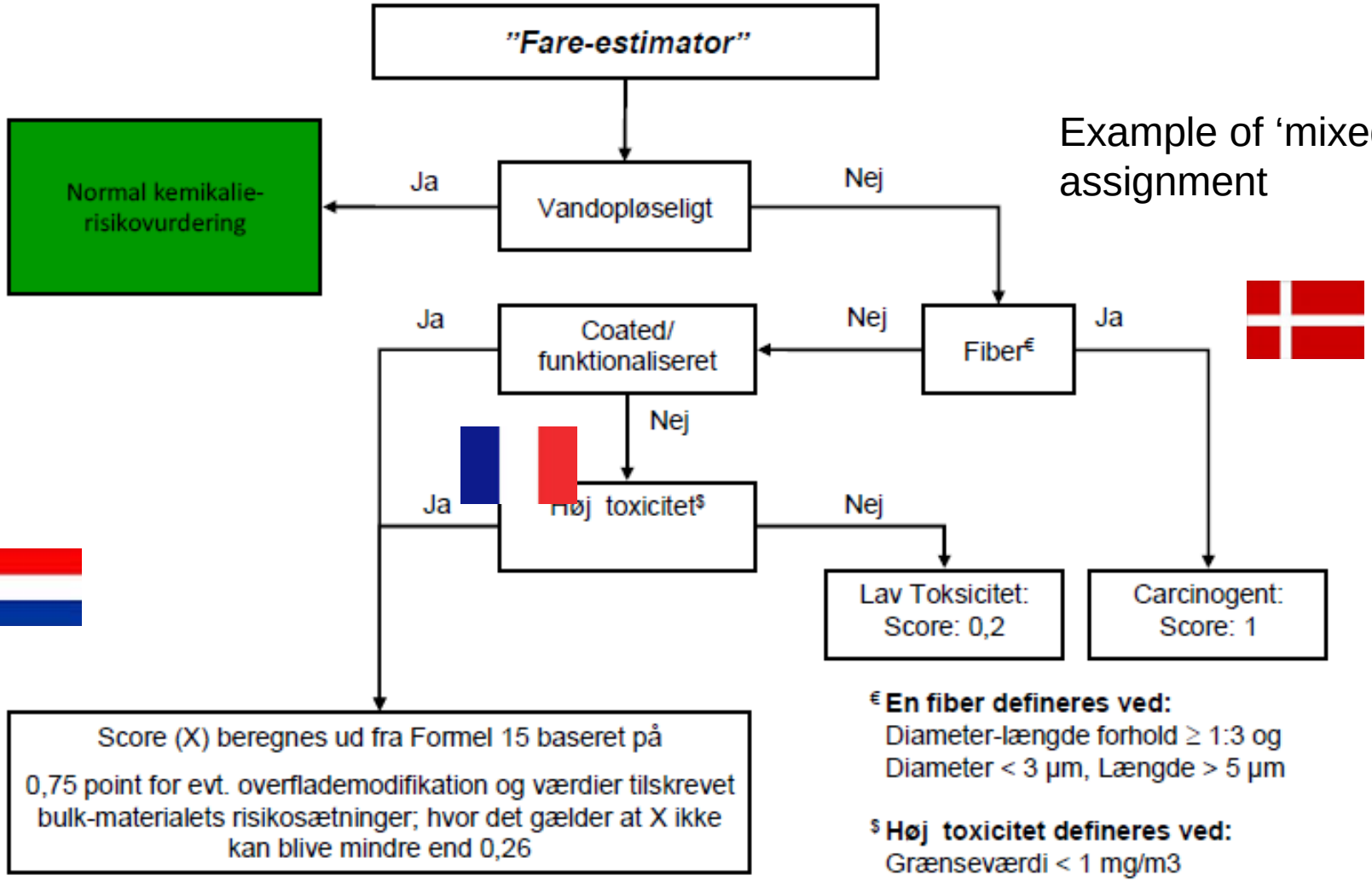
Currently available Risk Prioritization(Evaluation)/ CB tools

	Precautionary Matrix	Risk Prioritization	Web-available spreadsheet www.nanotechnologie.admin.ch
	NanoCB tool (Paik & Zalk 2009)	Control Banding	Table/published paper
	ANSES NanoCB tool	Control Banding	(Web-available) Report www.anses.fr
	Stoffenmanager Nano 1.0	Risk Prioritization	Web-based tool http://nano.stoffenmanager.nl/
	NanoSafer	Risk Evaluation (semi- quantitative)	Web-based tool http://nanosafer.i-bar.dk/

Hazard/ severity parameters

					
parameter	score	score	binary	binary	mixed
size	☺	☻	☻	☻	☻
shape	☺	☻	☻	☻	☻
solubility	☻	☻	☻	☻	☻
surface chemistry/ redox	☻	☻	☻		
stability	☻		☻		
CMR		☻	☻	☻	
dermal tox		☻	☻		
asthmagen		☻			
parent material/ C&L		☻	☻	☻	☻ ☻

Figur 8.5: Flowdiagram til evaluering og skalering af det toksikologiske fareniveau



Example of 'mixed' assignment

Validity domains

Emission *Transmission* *Immission*

	Emission Potential			Immission/ exposure	
	CONTROL BANDING			RISK BANDING	
Source Domain					
Synthesis	(☺)	☻		☻	
Powder Handling	(☺)	☻	☻	☻	☻ ☻
Ready-to-use products	(☺)		☻	☻	
Machining/ abrasion	(☺)			☺	

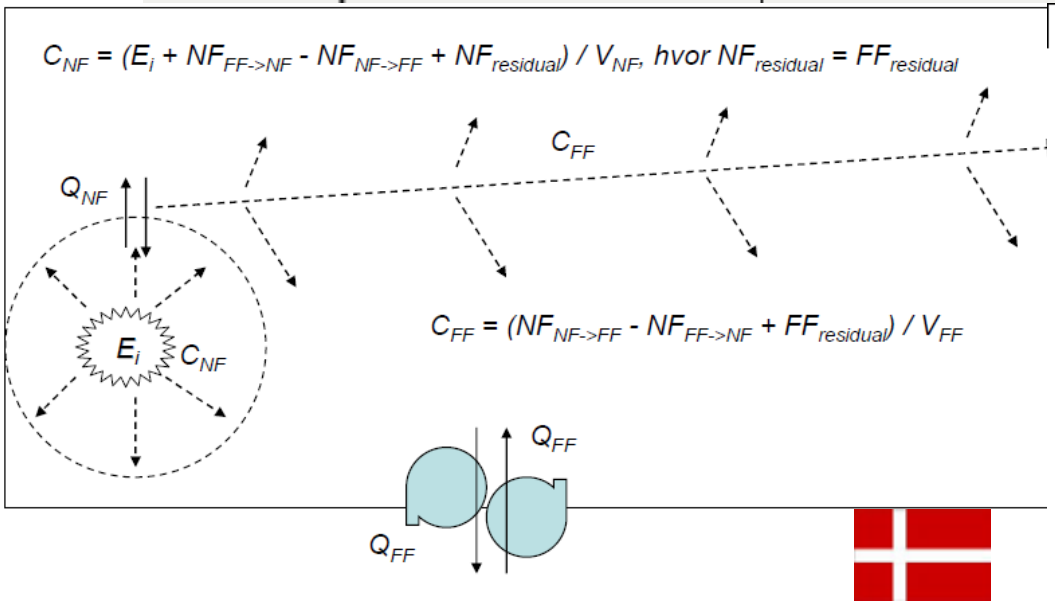
Example of allocation Exposure Band: Emission potential

Physical form	Solid	Liquid	Powder	Aerosol
Emission Potential	**EP1**	**EP2**	**EP3**	**EP4**
	Specific cases of band modification due to the natural tendency of the material			
	Friable solid (+2 bands)	**Highly volatile liquid (+1 band)**	**High or moderate dustiness powder (+1 band)**	**-**
	Specific cases of band modification due to process operation			
	Dust generated by external forces (+3 bands) **Melting (+1 band)** **Dispersion in liquid (+1 band)**	**Powder generated by evaporation (+1/+2 band according to dustiness of the powder)** **Spraying (+2 bands)** **No generation of aerosol during process: (-1 band)**	**Spraying (+1 band)**	**-**

Example of allocation Exposure Band: Immission/ BZ Conc

B = [(Cnf) + (Cff) + (Cds)] * ηimm * ηppe * th * fh
Cnf = E * H * ηlc_nf * ηgv_nf
Cff = E * H * ηlc_ff * ηgv_ff
Cds = E * a

Exposure band	Range scores
1	0 – 0.002



Gennemsnitlig daglig eksponering i nærområdet (8 timer)

Toksicitet / Eksponering	0,76 - 1,00	0,51 - 0,75	0,26 - 0,50	0,00 - 0,25
>1,00	RL5	RL5	RL5	RL5
0,51 - 1,00	RL5	RL5	RL4	RL4
0,26 - 0,50	RL5	RL4	RL4	**RL3**
0,11 - 0,25	RL4	RL4	RL3	RL2
< 0,10	RL4	RL3	RL2	RL1

$Exp_{NF} = C_{NF} / OEL_{recalculated\ to\ SA}$

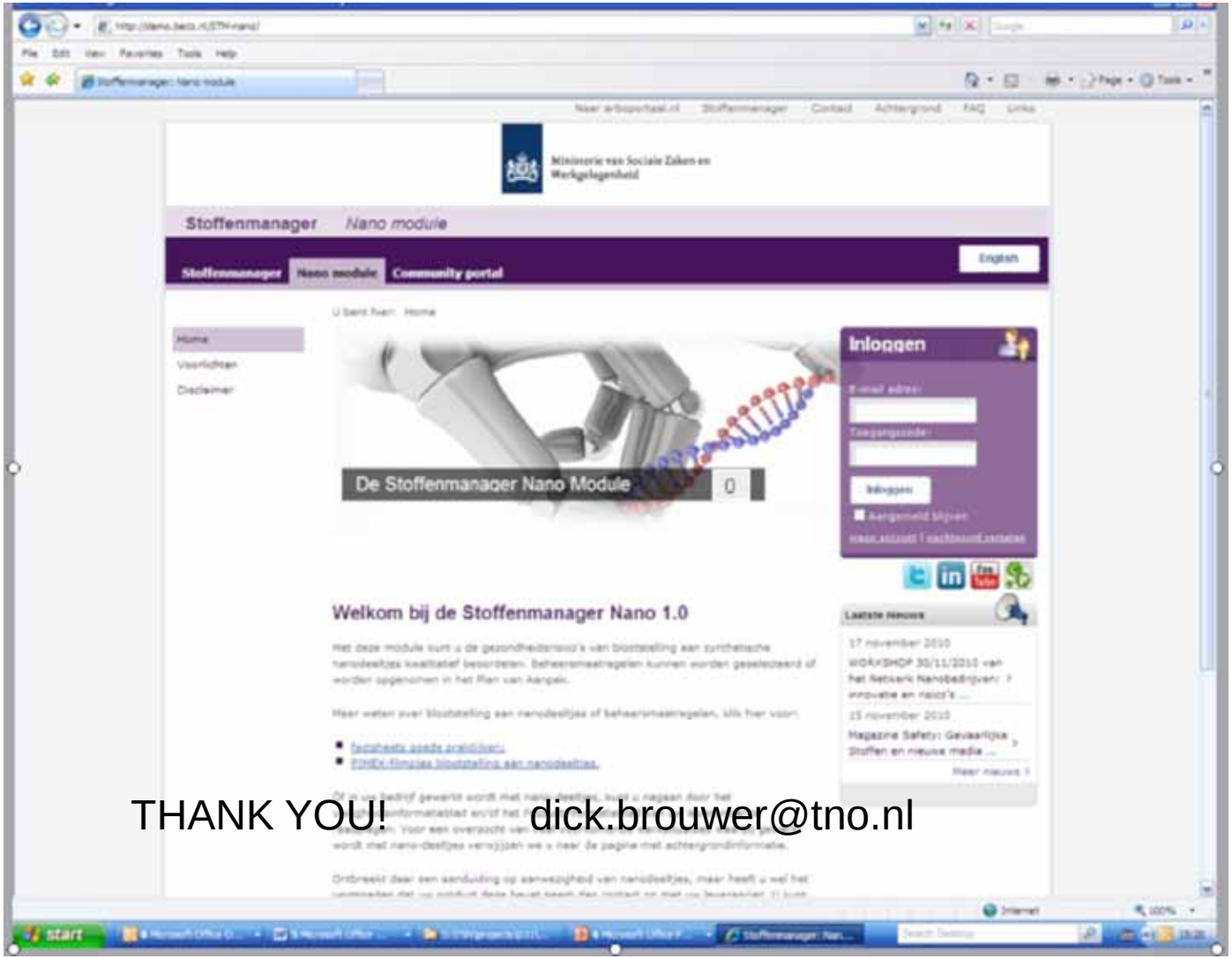
Conclusions and Future actions (1)

- Control Banding/ Risk Prioritization tools
  - Currently several ‘tools’ (web-based) available for risk management purposes
    - Hazard and Exposure bands:
      - differences how to assign and what parameters addressed
      - Independent “entities’
    - Need for ‘calibration’/ performance check
    - Need to fill knowledge gaps e.g. by expert elicitation
    - Need to extend ‘validity domain for exposure
  - Currently evaluated/ discussed within ISO CEN TC229

Conclusions and Future actions (2)

- Exposure models

- NMP 2011.1.3-2 project proposal focused on exposure modeling failed 1st stage;
  - Pooling of (future) exposure data needed:
    - Harmonization of measurement strategy etc
    - International (EU_US)Workshop 2010 NL; (2011 US)
    - DATAbase Initiative in EU – linkage to US initiative is aimed
    - National programs Measurement/ Campaigns (e.g. Germany, Netherlands, France, USA, …etc should populate database



THANK YOU! dick.brouwer@tno.nl