Risk Assessment in Control Banding

Susan Ripple

ERAM – Exposure Risk Assessment and Management

A new name for a proven process? Why Control Banding now?

- IH's losing the preferential status for exposure assessment
- IH's perceived as 'pump hangers' because we don't characterize the 'risk' associated with exposure control
- We need to re-invent ourselves to our clients as "Exposure Risk Assessors and Risk Managers"

We need to ‘speak the language’ of the decision-makers ($$$$$)

- We need to talk about risk management controls in terms of “risk”
  - Risk relative to non-compliance with OELs
  - Risk relative to known toxicology without OELs
  - Risk of compliance with OELs
- How do we do that today?
  - We rarely speak in terms of relevant risks (maybe only ‘compliance’)
- We are not making ourselves RELEVANT

Question!

- Just how irrelevant are Industrial Hygienists in ERAM ?

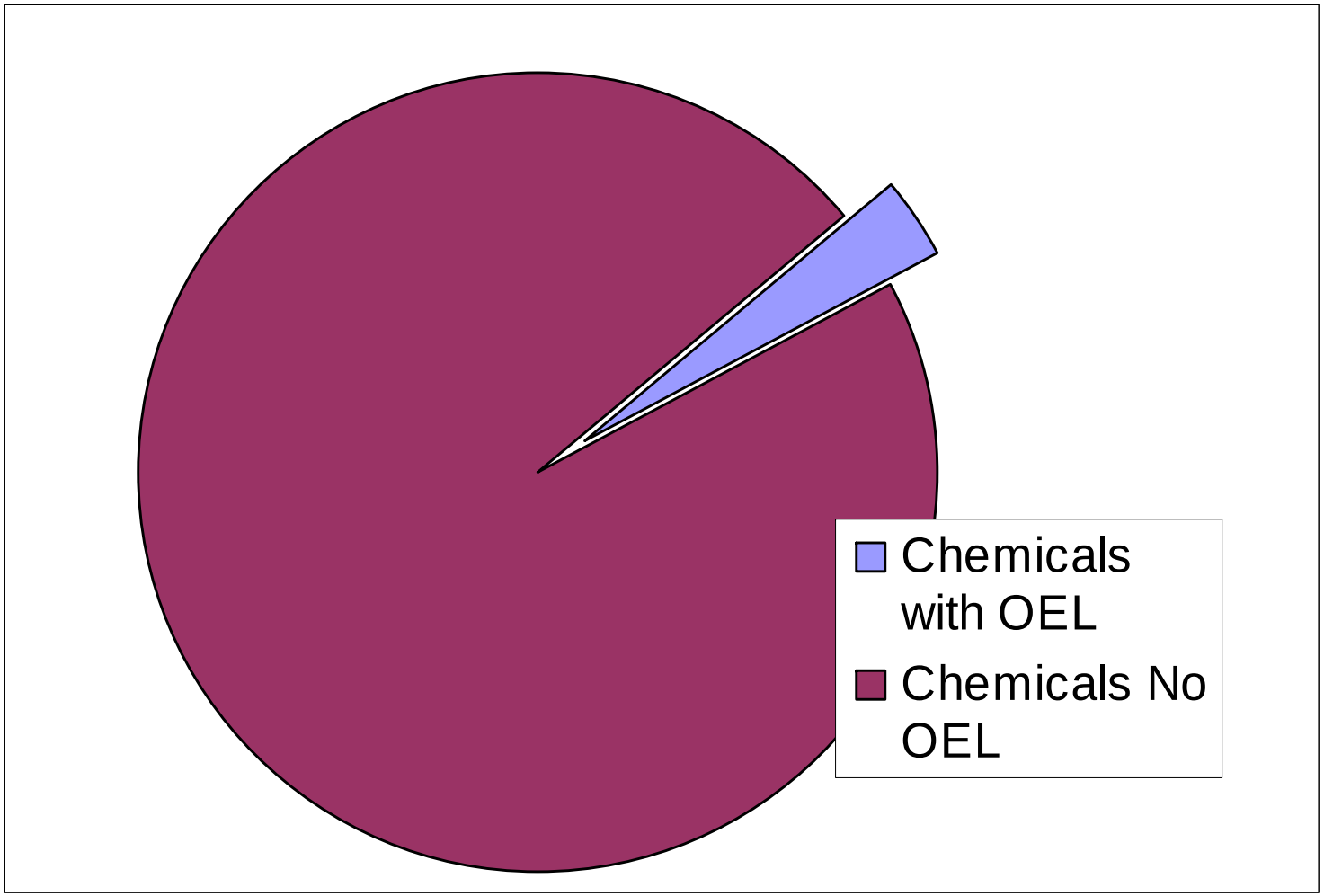
The landscape seems bare!

- ~21,000,000 commercially available chemicals
- 107,067 REACH* registrations (1-3-11) for >1000 tons production volume or those of high concern
- But…only ~ 500 PELs, ~ 650 RELs, ~ 125 WEELs, ~ 650 TLVs

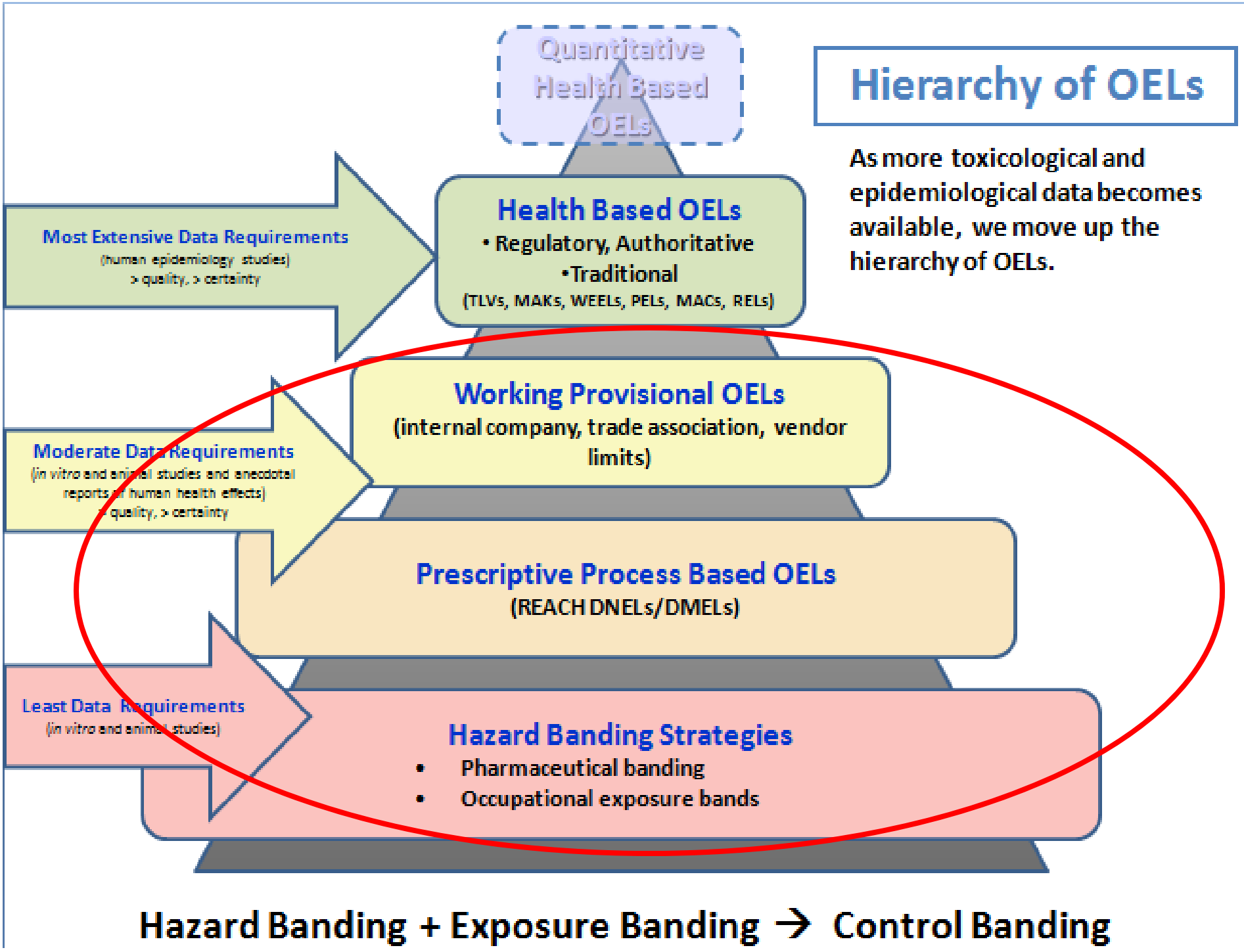
REACH – Registration, Evaluation, Authorization, and Restriction of Chemicals

But, without OELs, how do we improve our position?

Chemicals With OELs



"You can't always get what you want, but if you try some times you might find, you'll get what you need" – Mick Jaeger

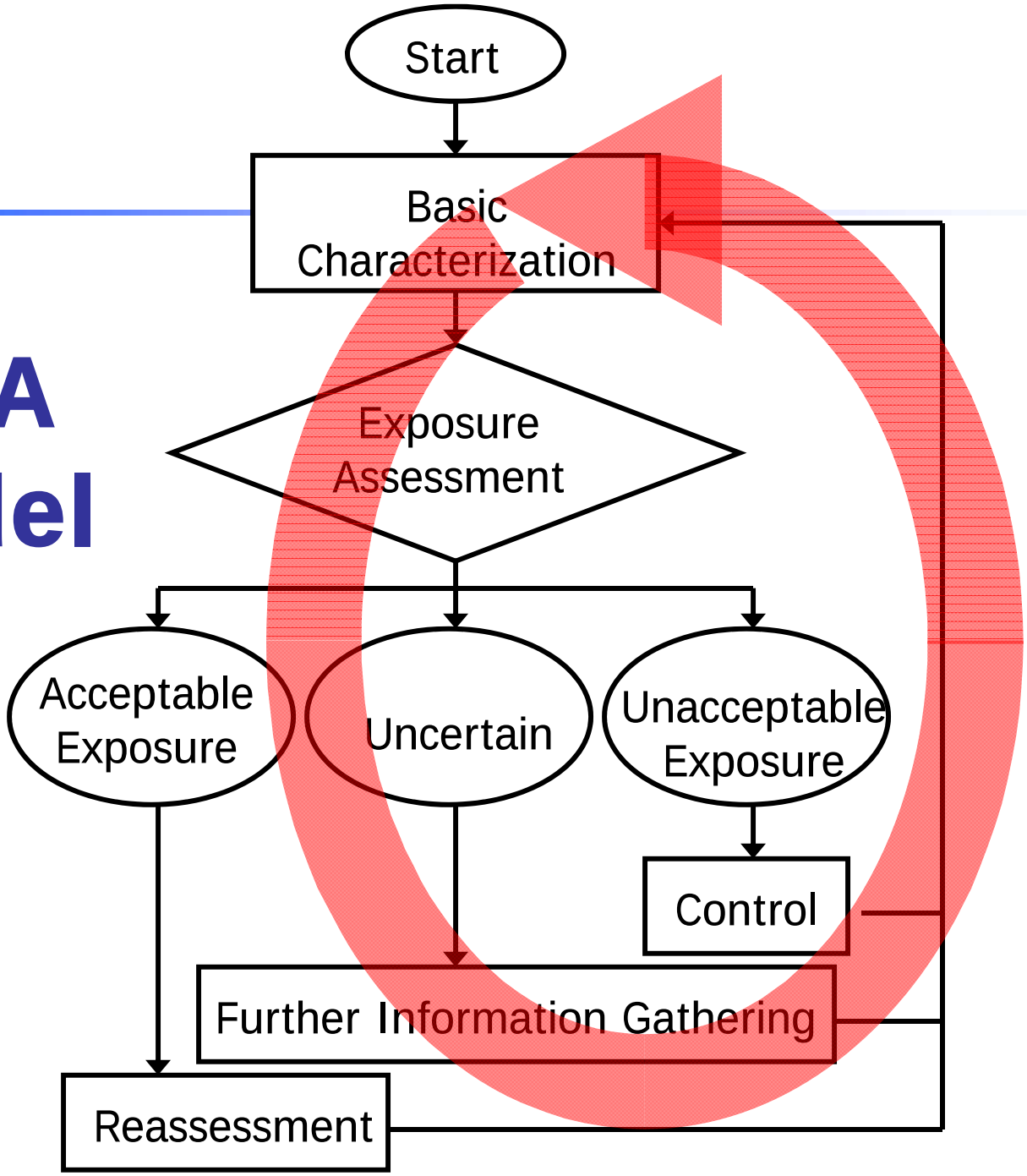

Quantitative Health Based OELs
Hierarchy of OELs
As more toxicological and epidemiological data becomes available, we move up the hierarchy of OELs.
Most Extensive Data Requirements
(human epidemiology studies)
> quality, > certainty
Health Based OELs
• Regulatory, Authoritative
•Traditional
(TLVs, MAKs, WEELs, PELs, MACs, RELs)
Working Provisional OELs
(internal company, trade association, vendor limits)
Moderate Data Requirements
(in vitro and animal studies and anecdotal reports of human health effects)
> quality, > certainty
Prescriptive Process Based OELs
(REACH DNELs/DMELs)
Least Data Requirements
(in vitro and animal studies)
Hazard Banding Strategies
• Pharmaceutical banding
• Occupational exposure bands
Hazard Banding + Exposure Banding → Control Banding

Working OELs

- **Occupational Exposure Banding** provides a mechanism for the evaluation of hazard and risk to offset the misconceptions by employers and workers that a substance must be non-toxic if there is not an OEL!

Integration of Control Banding Concepts into Exposure Risk Management System

AIHA Model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Exposure Assessment
Acceptable Exposure
Uncertain
Unacceptable Exposure
Control
Further Information Gathering
Reassessment

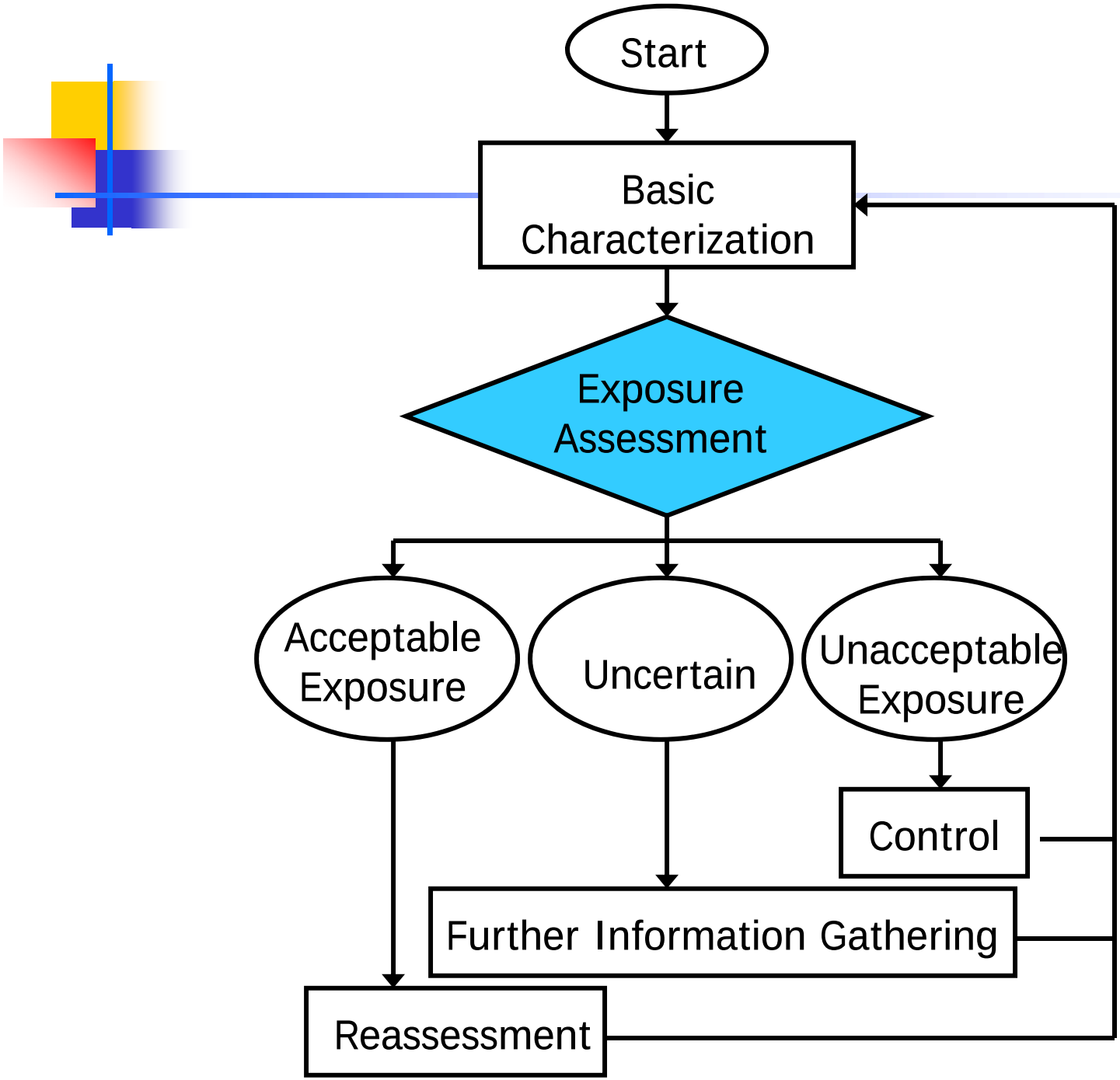
Control Banding Useful?

Control banding concepts offer a significant opportunity to improve exposure assessment efficiency and effectiveness **if . . .**

integrated into a tiered, continuous improvement approach to exposure risk assessment and management.

COSHH Essentials

substance allocated to a hazard group or hazard band + substance/ operation allocated to an exposure predictor band → risk assessment: compare hazard band to exposure predictor band → determine control needed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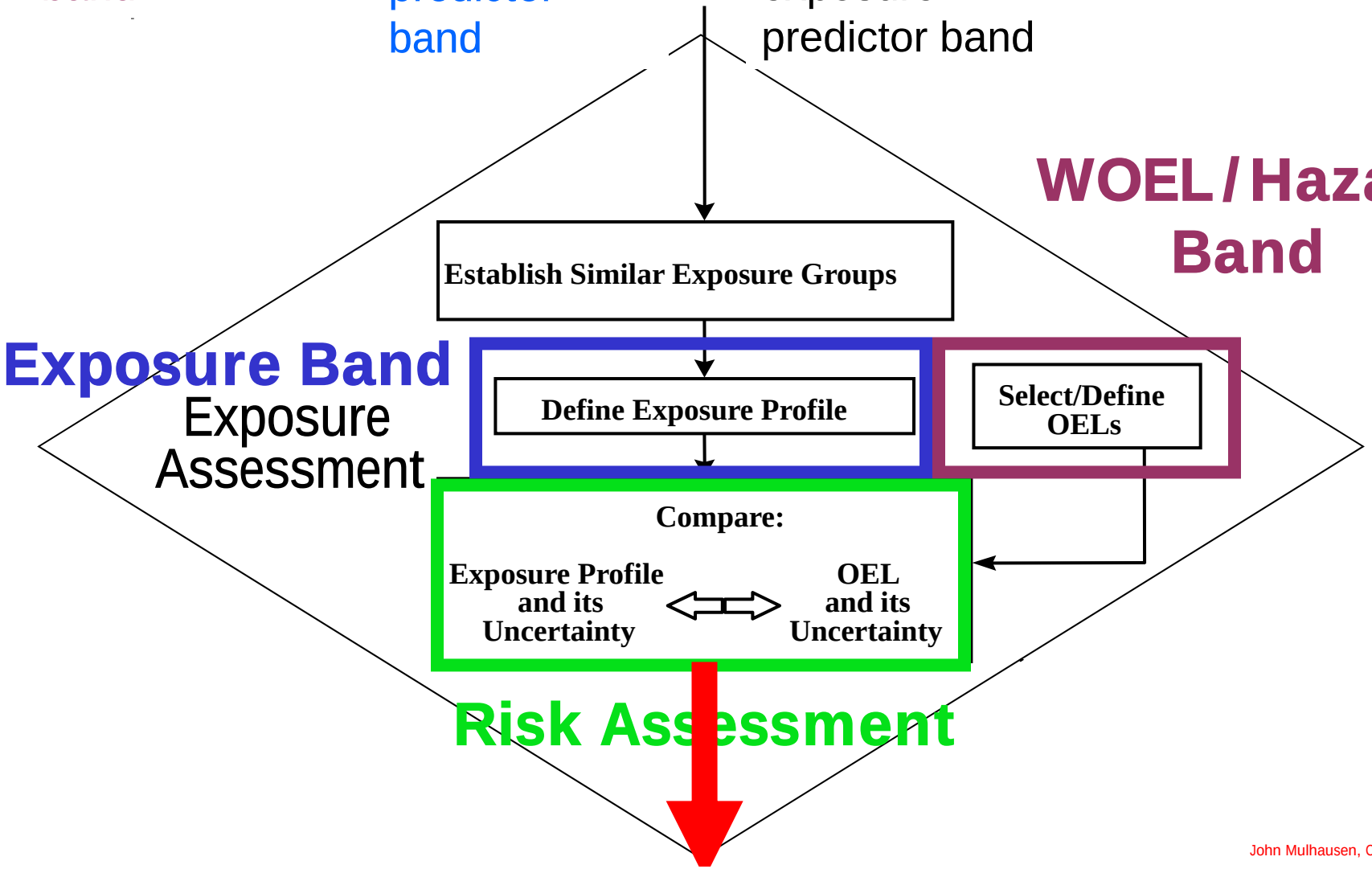
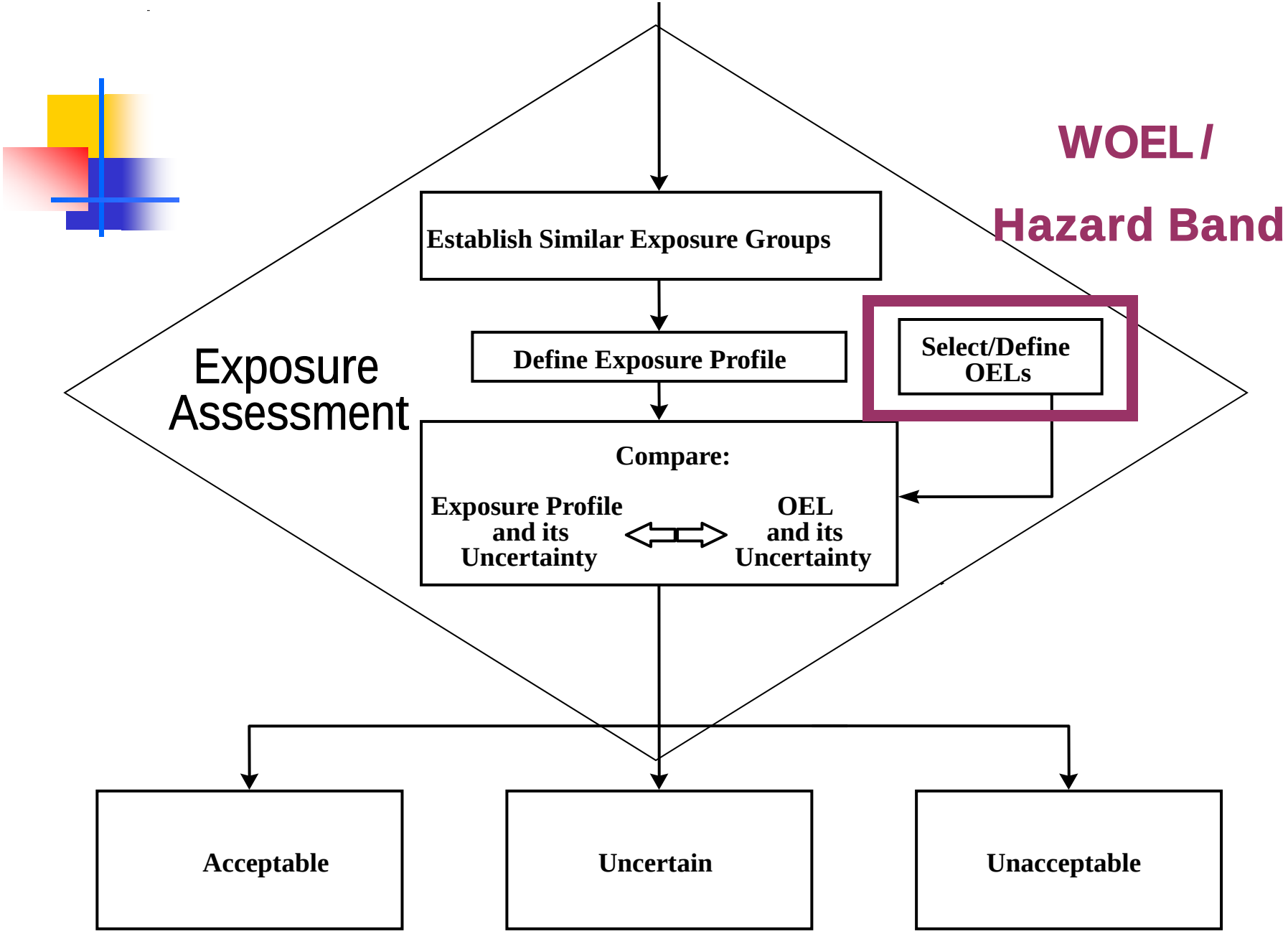
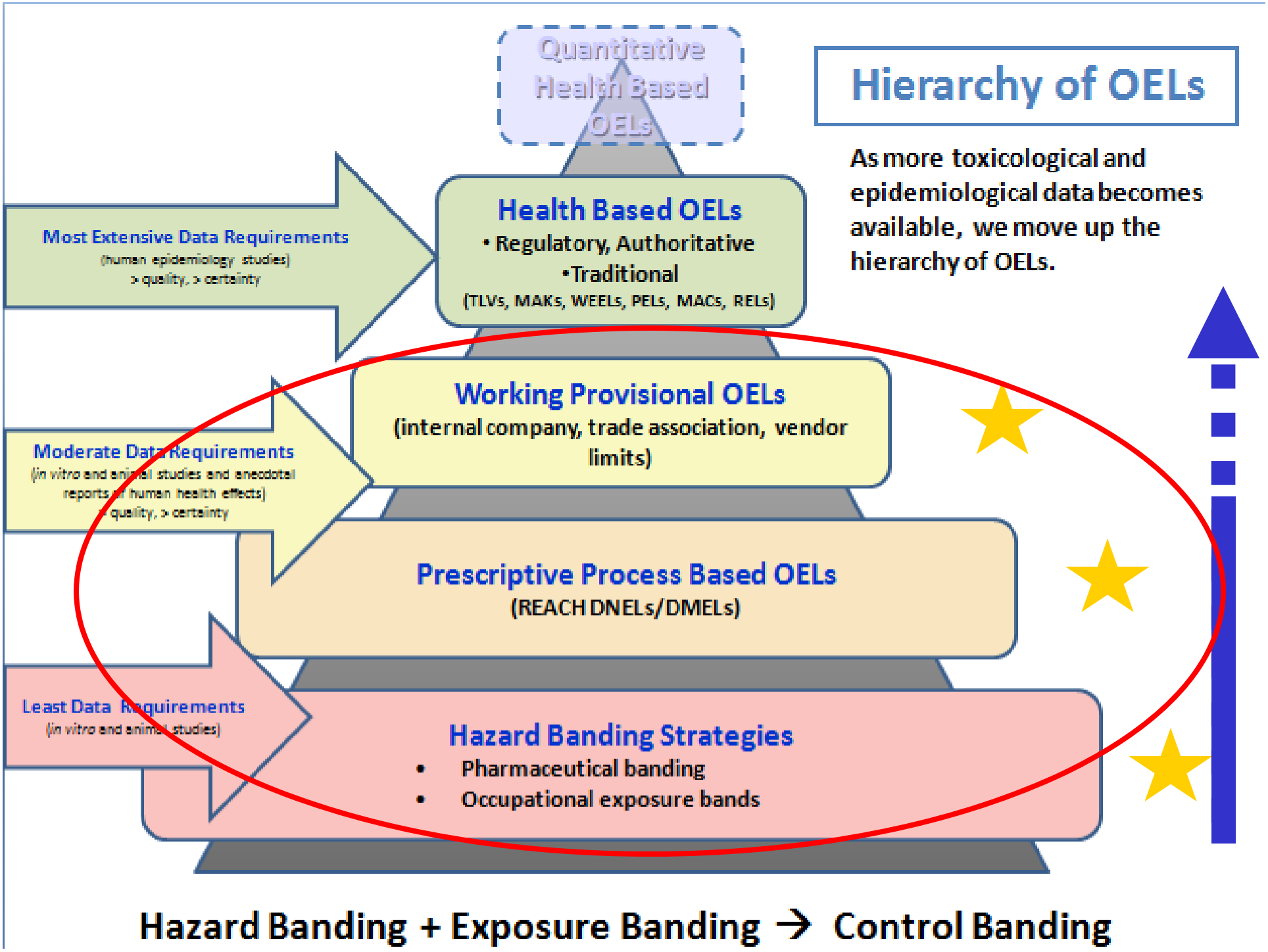



WOEL /
Hazard Band
Exposure Assessment
Establish Similar Exposure Groups
Define Exposure Profile
Select/Define OELs
Compare:
Exposure Profile and its Uncertainty
OEL and its Uncertainty
Acceptable
Uncertain
Unacceptable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Hazard Banding Strategies
• Pharmaceutical banding
• Occupational exposure bands
Hazard Banding + Exposure Banding → Control Banding

Example: COSSH Essentials

Hazard Group vs. Target Exposure Range		
Hazard group	**Target airborne concentration range**	**R phrases**
A -Skin and eye irritants	>1-10 mg/m3 dust >50-500 ppm vapor	R36, R38 All substances that do not have R phrases in groups B - E
B - Harmful on single exposure	>01-1 mg/m3 dust >5-50 ppm vapor	R20/21/22, R40/20/21/22
C -Severely irritating & corrosive, skin sensitizers	>0.01-0.1 mg/m3 dust >0.5-5 ppm vapor	R48/20/21/22, R23/24/25, R34, R35, R36/37, R37/38, R36/37/38, R37, R39/23/24/25, R41, R43
D -Very toxic on single exposure, reproductive hazard	< 0.01 mg/m3 dust < 0.5 ppm vapor	R48/23/24/25, R28/27/28. R39/26/27/28, Carc Cat 3 R40, R60. R61, R62, R63
E - Carcinogen, occupational asthma	*Seek Specialist Advice*	Muta Cat 3 R40, R42, R42/43, R45, R46, R49
S: Skin and eye contact	*Prevention or reduction of skin and/or eye exposure*	R21, R24, R27, R34, R35, R36, R38, R41, R43, R48/21, R48/24, plus R -phrase combinations containing these. Skin

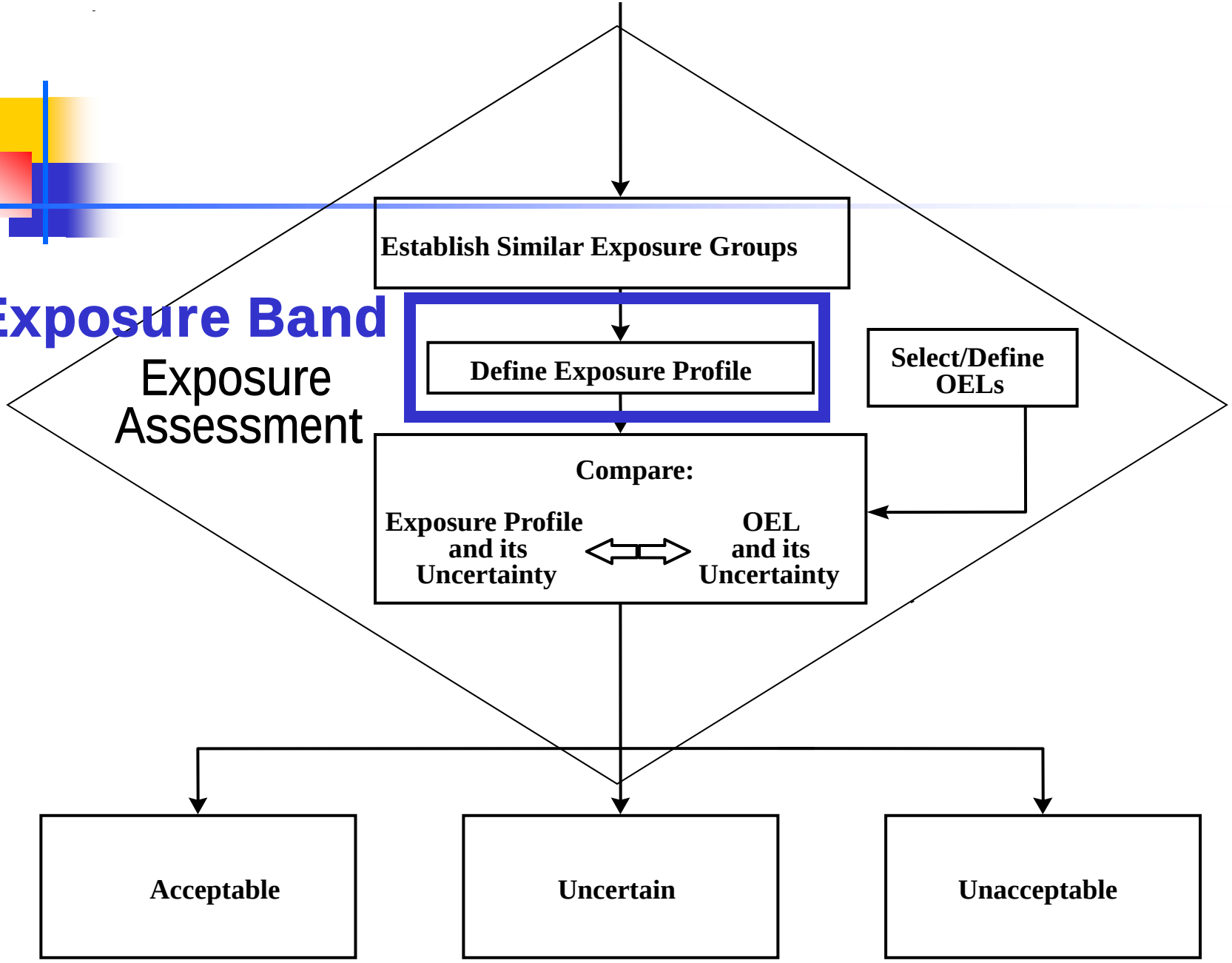
WEEL Banding Matrix

		Virtually Non-Toxic	Low Toxicity	Moderate Toxicity	Toxic	High Toxicity	
Criterion	**ND**	**A**	**B**	**C**	**D**	**E**	**Comments/Rationale**
Acute toxicity (Rat oral LD50)		**>2,000 mg/kg** Rats: 2820 to 4480 mg/kg Mice: 5520 mg/kg Dogs: >5000 mg/kg, dog emesis at 250 mg/kg	300-2,000 mg/kg	50-300 mg/kg	5-50 mg/kg	<5 mg/kg	
Acute toxicity (Rat inhalation LC50)- Not Available		>10,000 ppm	>10,000 ppm	1000-10,000 ppm	100-1000 ppm	**1-100 ppm**	Extrapolated from comments only
Sensory irritation (RD50)- Not Available		>3,000 ppm	>3,000 ppm	300-3000 ppm	30-300 ppm	**1-30 ppm**	Corrosive to respiratory tract
Skin or eye irritation		mild to moderate	moderate to severe	severe to corrosive	**corrosive**	**corrosive**	Corrosive to eyes, skin and respiratory tract; Inhalation of high concentrations can cause pulmonary edema
Irritation threshold (ppm)- Not Available		>1000	100-1000	10-100	1-10	<1	
Target organ toxicity NOEL **Neurotoxicity**		>1000 ppm >100 mg/kg/d	**>1000 ppm** **10-100 mg/kg/d**	**100-1000 ppm** **1-10 mg/kg/d** **Moser: 16 mg/kg/d** **LOAEL Neurotox**	10-100 ppm 0.1-1 mg/kg/d	1-10 ppm <0.1 mg/kg/d	
Severity of target organ toxicity		**severity of the toxicity can push the above NOEL into a higher cell**					
Repro/dev tox NOEL		>300 mg/kg/d	30-300 mg/kg/d	3-30 mg/kg/d	**0.3-3 mg/kg/d** LOAEL 12.5 mg/kg/d (90d study in dogs)	**<0.3 mg/kg/d**	LOAEL 12.5 mg/kg/day (sodium salt) in dogs 90 day study showed degeneration of testicular germinal cell epithelium and syncytial giant cell formation
Reproductive toxicity		**severity of the toxicity can push the above NOEL into a higher cell**					
Developmental toxicity		**severity of the toxicity can push the above NOEL into a higher cell**					14 mg/kg/day was identified as a NOAEL for dev. Tox
Genetox		negative	equivocal	likely / limited or based on *in vitro*	**positive WOE including *in vivo***	positive WOE and potent	
Cancer dose-NOEL/NOAELs		>300 mg/kg/d	30-300 mg/kg/d	**3-30 mg/kg/d**	0.3-3 mg/kg/d	<0.3 mg/kg/d	
Carcinogenicity potential		**severity of the toxicity can push the above NOEL into a higher cell**					
Warning properties / odor		good: 0.04 ppm	good	fair to none	poor to none	poor to none	
OEL range (mcg/m3 and ppm)		≥1000	≥100, <1000	≥10, <100	≥1, <10	**<1**	
Skin notation		No	**Yes** **LD50=510 mg/kg**				greater than 200 mg/kd
Sensitization notation		No	Yes				

WOEL Example:
Hazard Bands → Working OELs

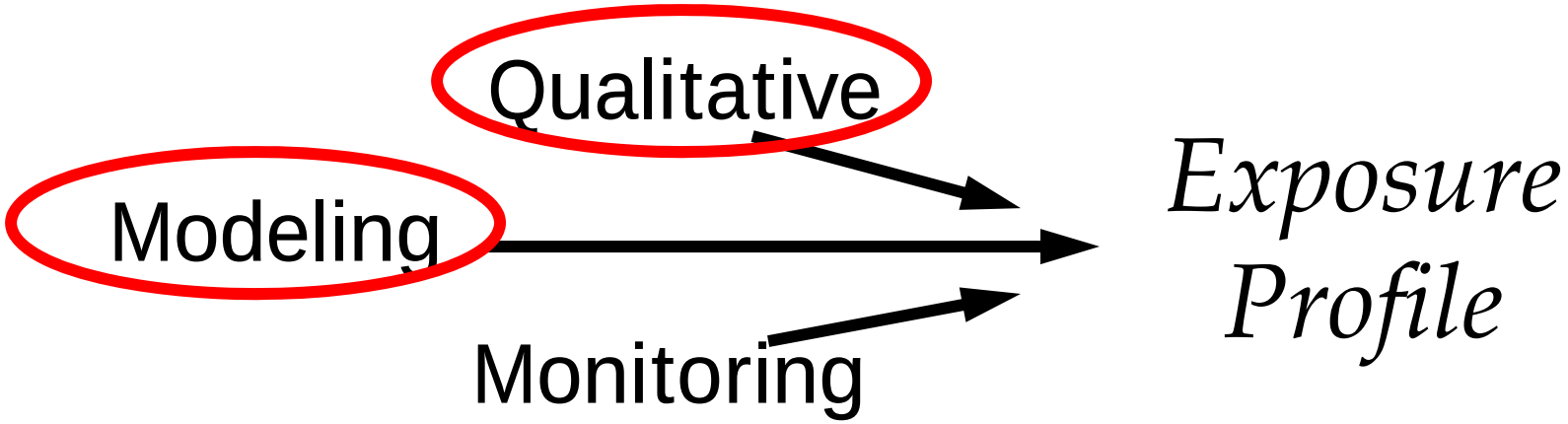
Type	Airborne Concentration Range	Units	WOEL Code
Particulate	>1 – 10	mg/m3	A-P
Particulate	>0.1 – 1	mg/m3	B-P
Particulate	>0.01 – 0.1	mg/m3	C-P
Particulate	>0.001 – 0.01	mg/m3	D-P
Particulate	≤ 0.001	mg/m3	E-P
Vapor	>50 – 500	ppm	A-V
Vapor	>5 – 50	ppm	B-V
Vapor	>0.5 – 5	ppm	C-V
Vapor	> 0.05 – 0.5	ppm	D-V
Vapor	≤ 0.05	ppm	E-V

Exposure Band



Integrated Approach:

Define Exposure Using All Available Information



Tools for Initial Assessment

Example: Exposure Estimate

Agent "X"

G= steady generation rate (mg/hour)

35 to 65 mg/hour

Q= steady ventilation rate (m^3/hour)

3.6 to 540 m^3/hour

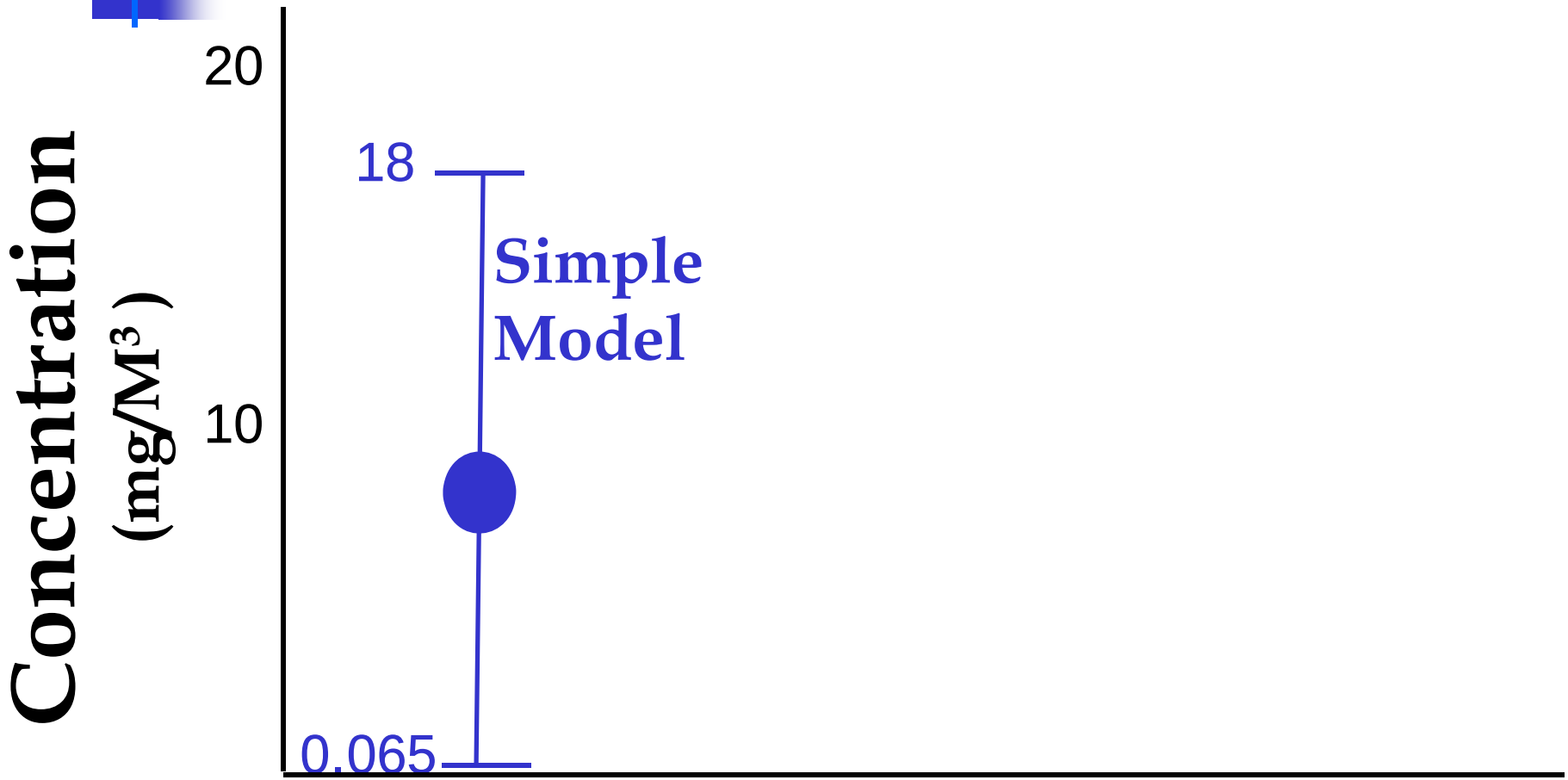
Simple Model:

$$C = \frac{G}{Q}$$

Worst Case $\quad C = \frac{65 \text{ mg/hour}}{3.6 \text{ m}^3\text{/hour}} = 18 \text{ mg/m}^3$

Best Case $\quad C = \frac{35 \text{ mg/hour}}{540 \text{ m}^3\text{/hour}} = 0.065 \text{ mg/m}^3$

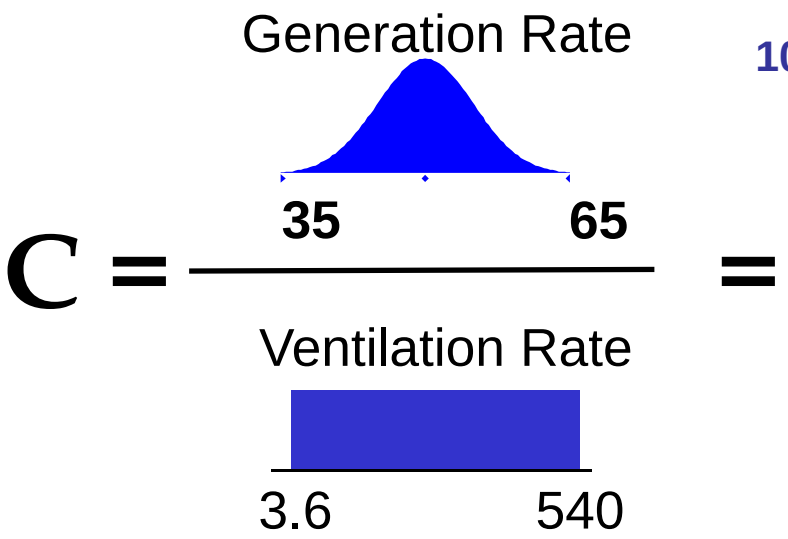
Uncertainty and Acceptability

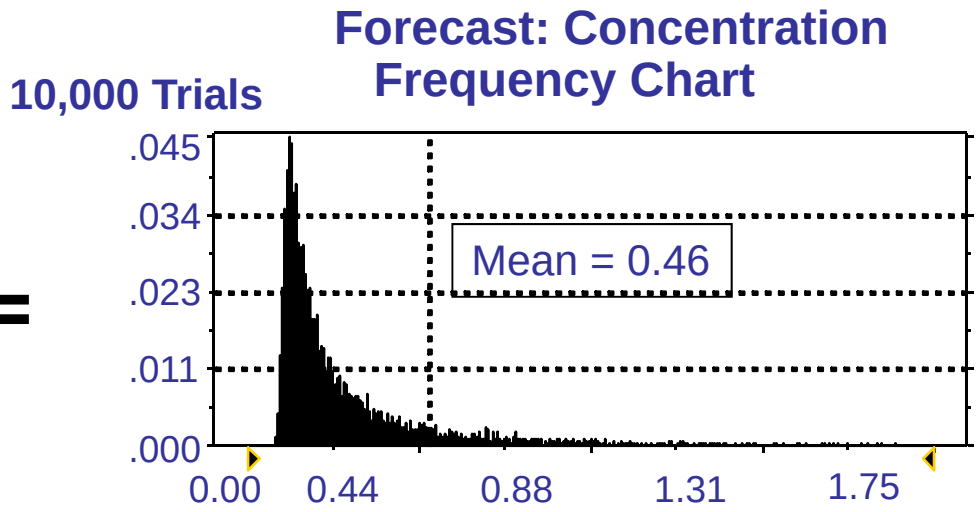


Example: Exposure Estimate

Statistical Modeling:
Monte Carlo
Uncertainty Analysis

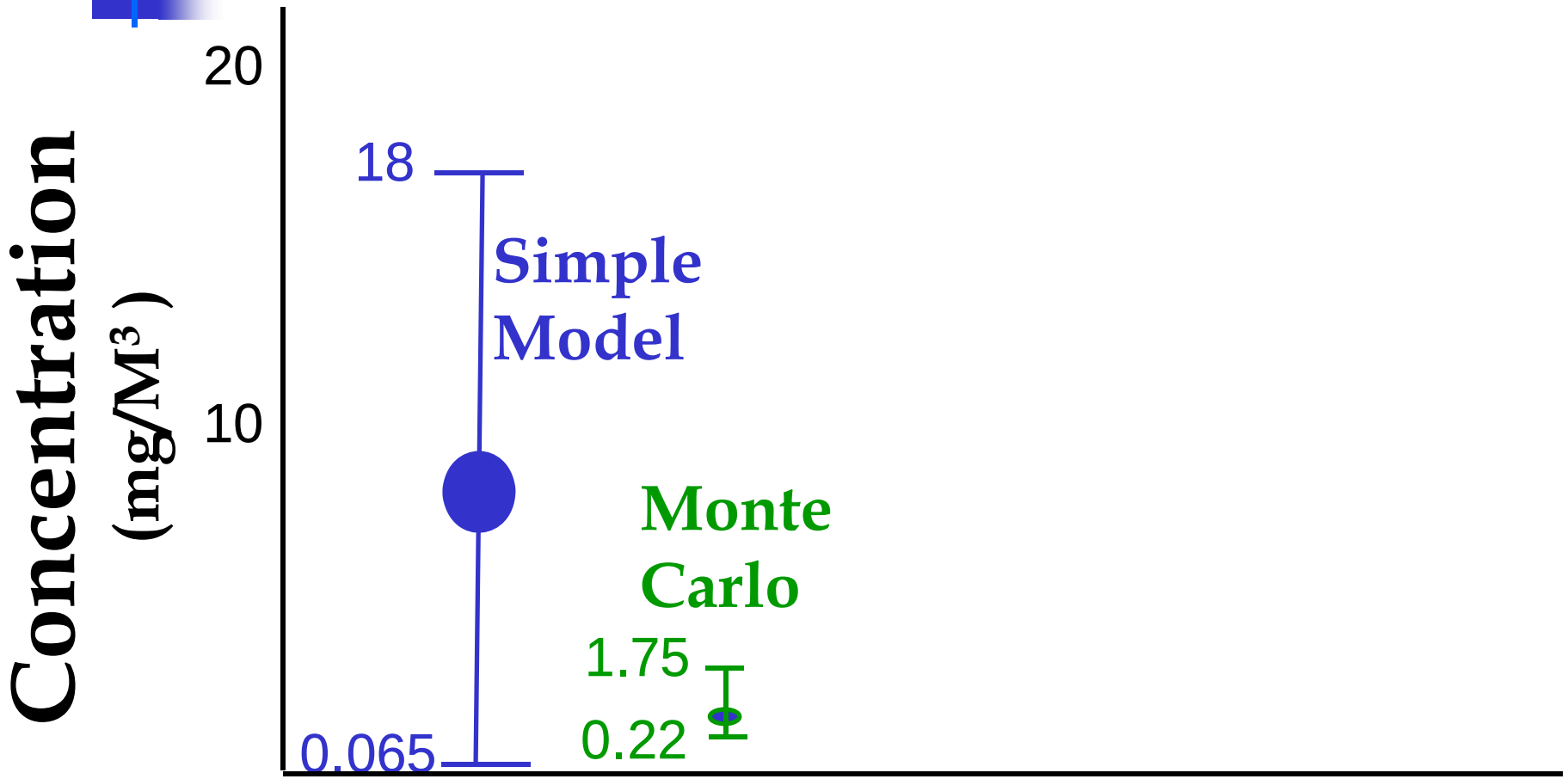
Agent "X"
G= steady generation rate (mg/hour)
35 to 65 mg/hour
Q= steady ventilation rate (m^3/hour)
3.6 to 540 m^3/hour





Certainty is 95.30% from 0.00 to 1.75 mg/m3

Uncertainty and Acceptability



COSHH Essentials

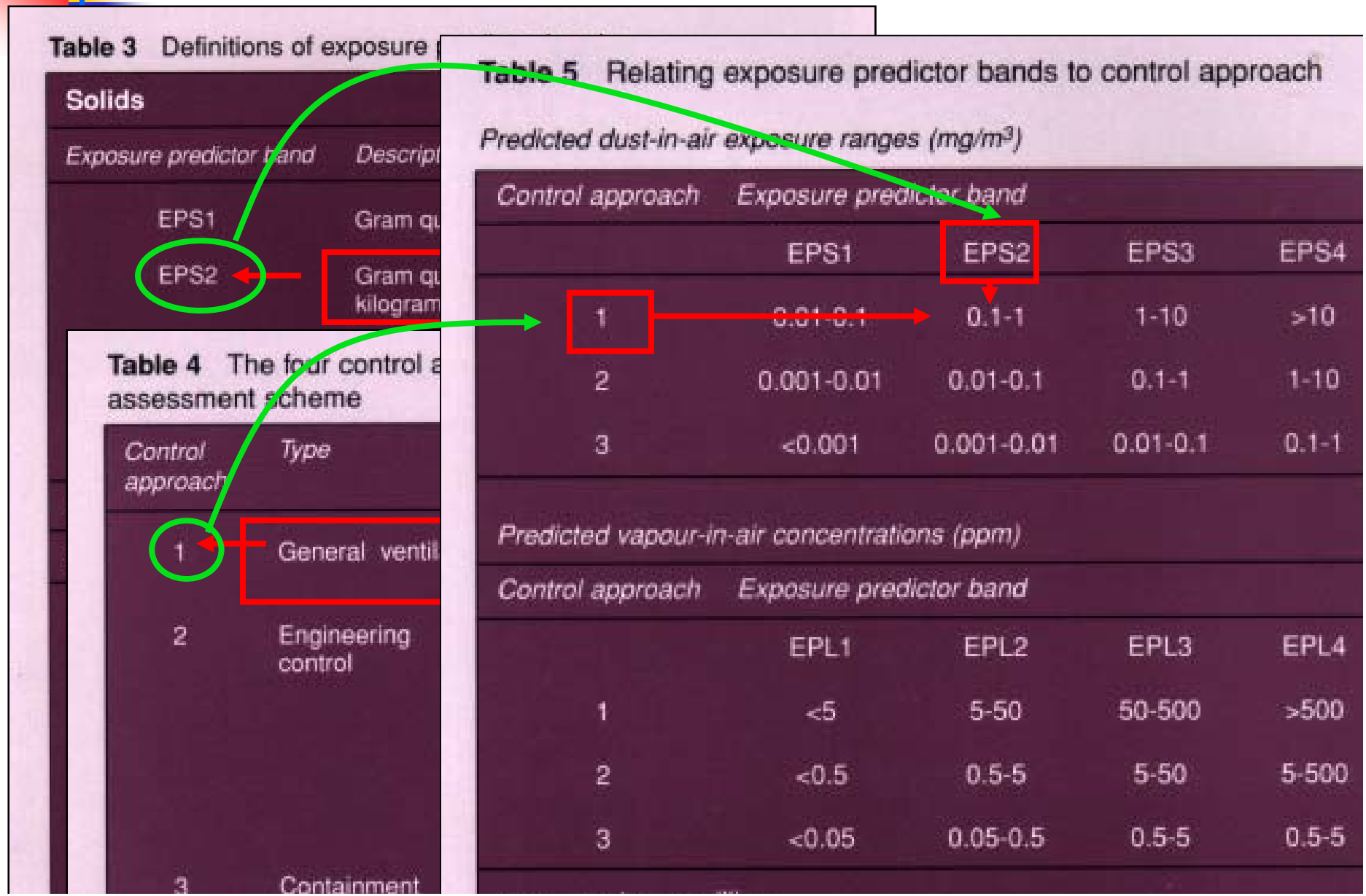


Table 3 Definitions of exposure

Solids

Exposure predictor band	*Descript*
EPS1	Gram qu
EPS2	Gram qu kilogram

Table 4 The four control a assessment scheme

Control approach	*Type*
1	General ventil
2	Engineering control
3	Containment

Table 5 Relating exposure predictor bands to control approach

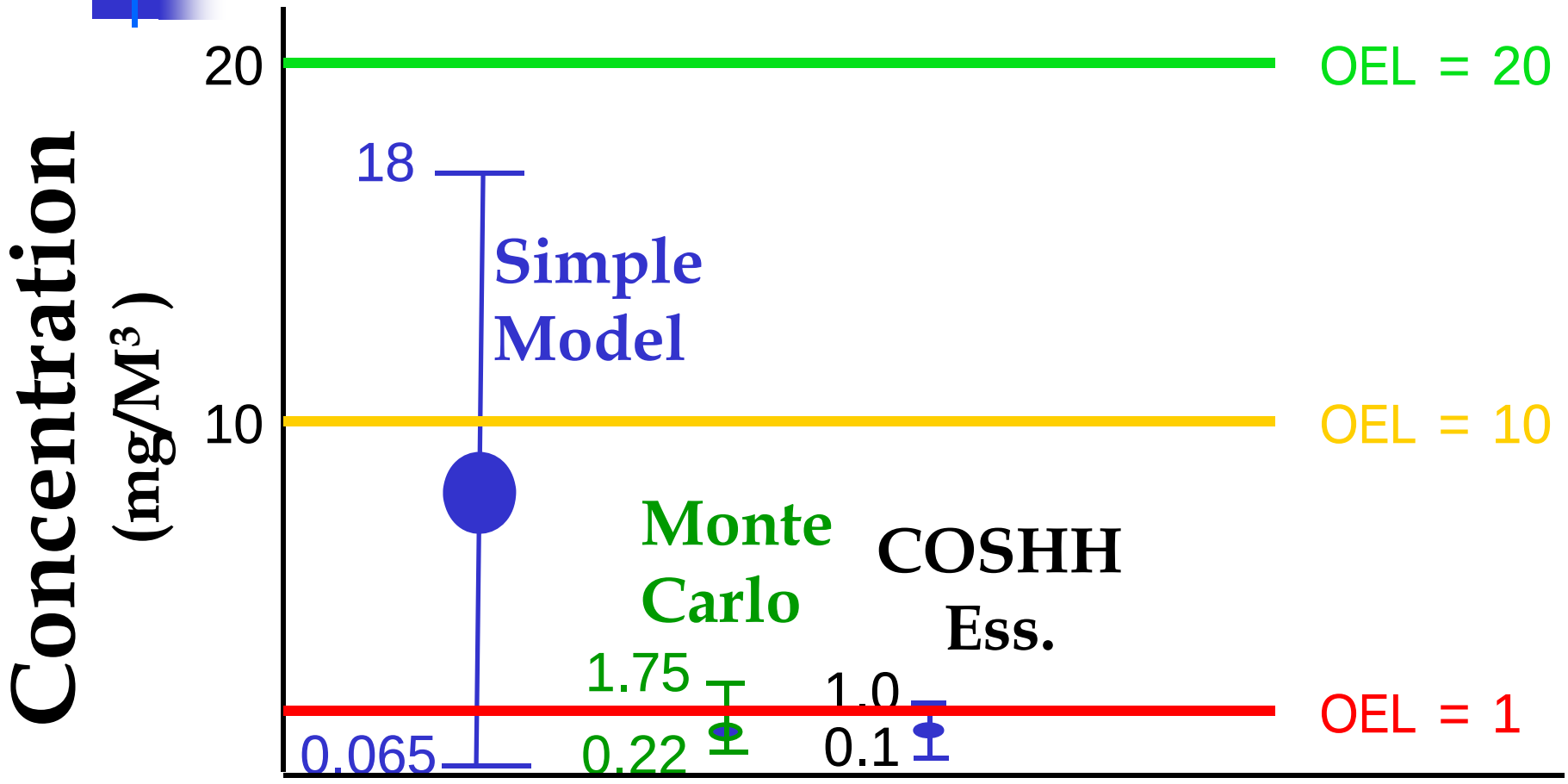
Predicted dust-in-air exposure ranges (mg/m³)

Control approach	*Exposure predictor band*			
	EPS1	EPS2	EPS3	EPS4
1	0.01-0.1	0.1-1	1-10	>10
2	0.001-0.01	0.01-0.1	0.1-1	1-10
3	<0.001	0.001-0.01	0.01-0.1	0.1-1

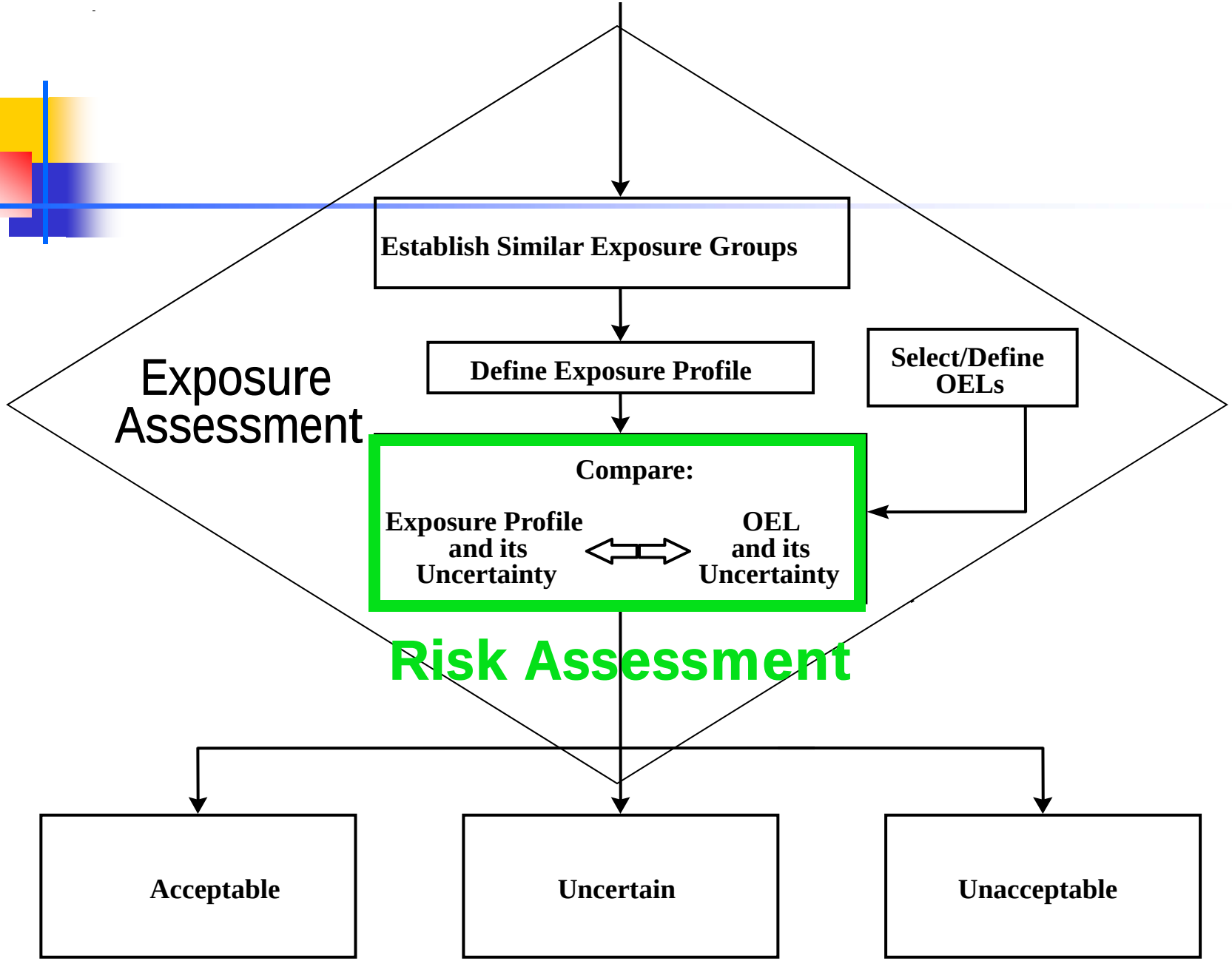
Predicted vapour-in-air concentrations (ppm)

Control approach	*Exposure predictor band*			
	EPL1	EPL2	EPL3	EPL4
1	<5	5-50	50-500	>500
2	<0.5	0.5-5	5-50	5-500
3	<0.05	0.05-0.5	0.5-5	0.5-5

Uncertainty and Acceptability

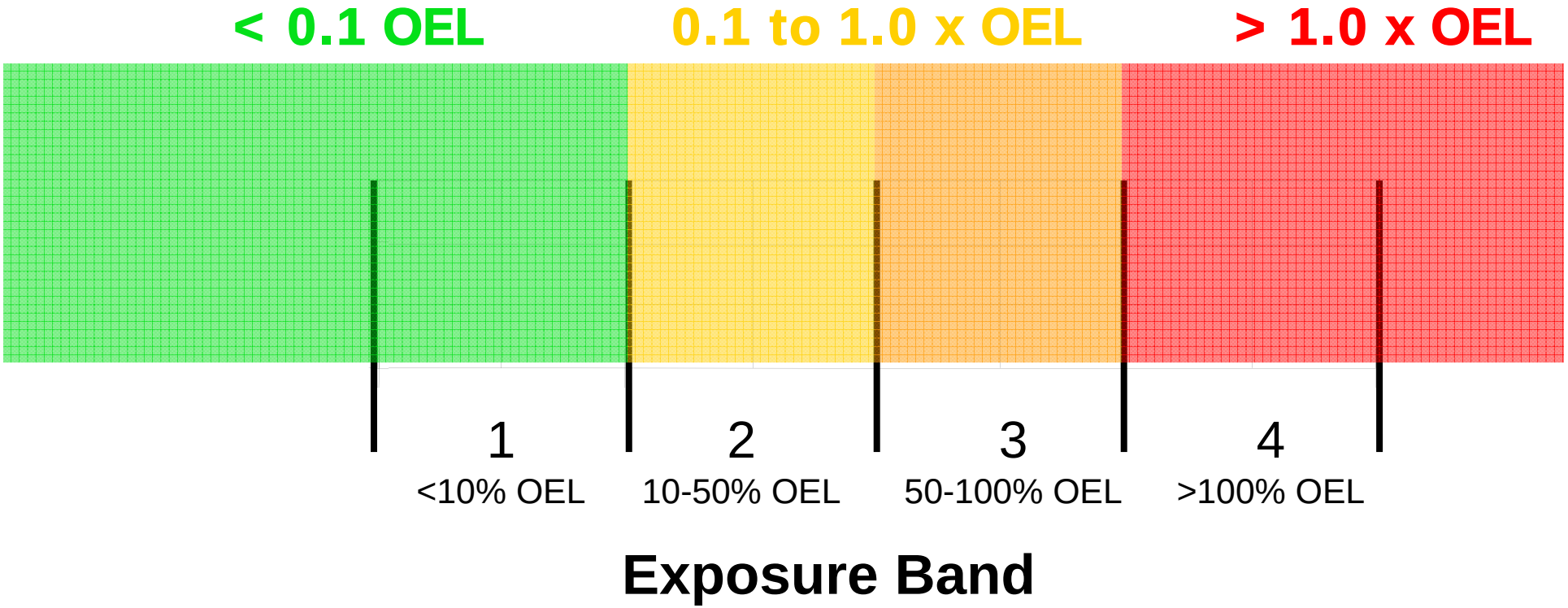


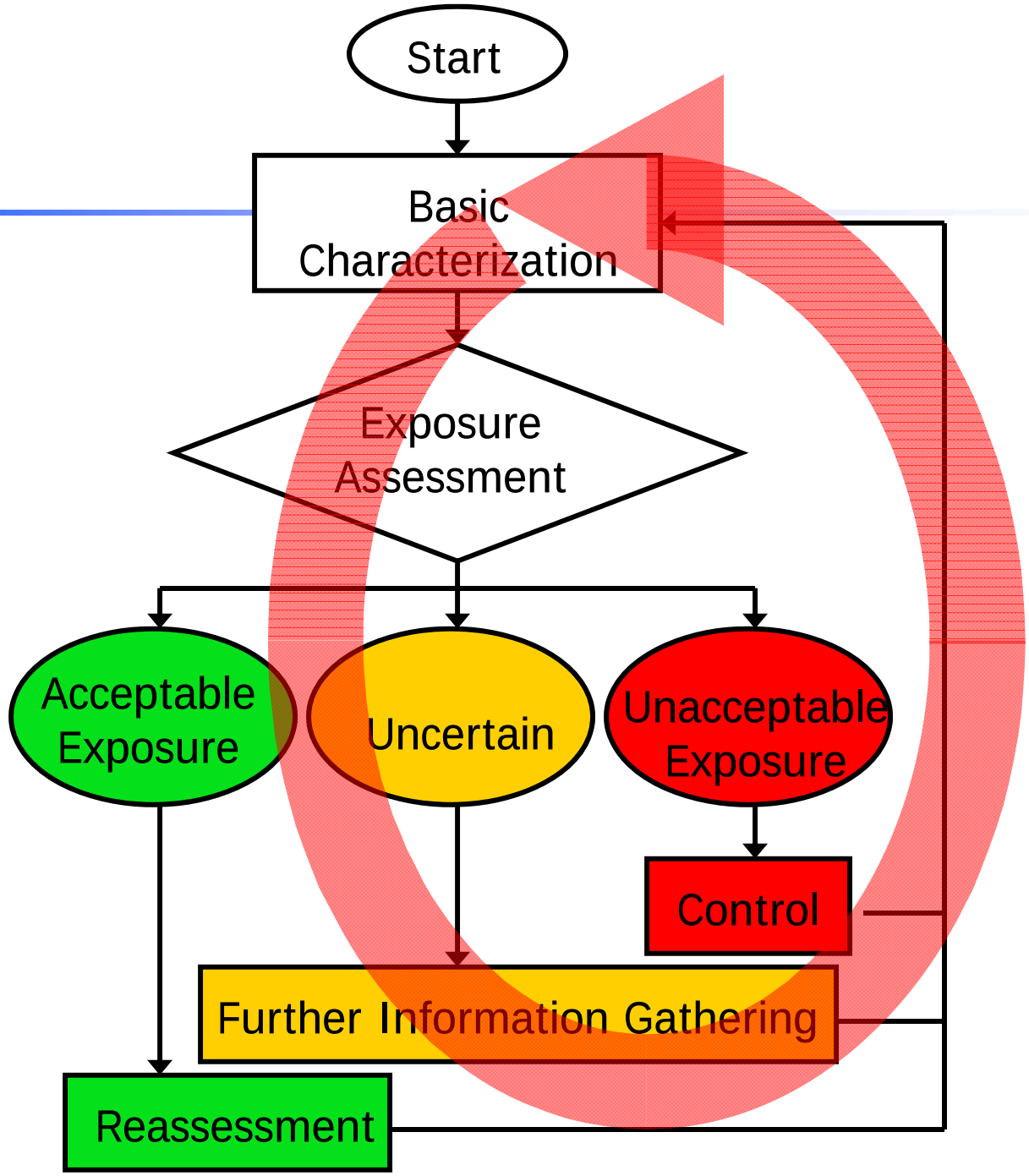
Which To Choose? **Acceptable?**


Establish Similar Exposure Groups
Exposure Assessment
Define Exposure Profile
Select/Define OELs
Compare:
Exposure Profile and its Uncertainty
OEL and its Uncertainty
Risk Assessment
Acceptable
Uncertain
Unacceptable

Initial Exposure Assessment: Rate Exposure Relative to OEL

Rate Upper 95%ile of Exposure Profile

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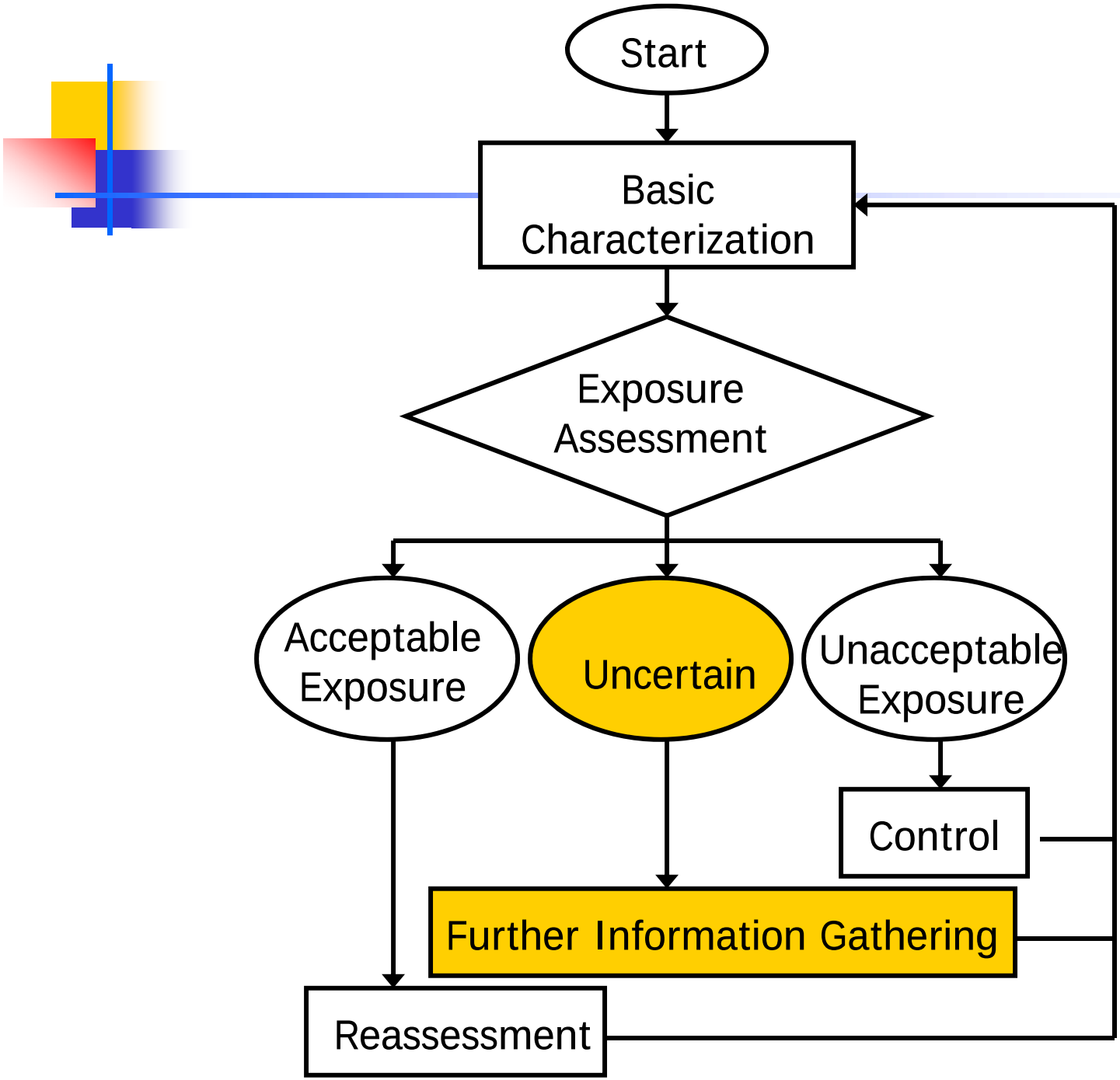
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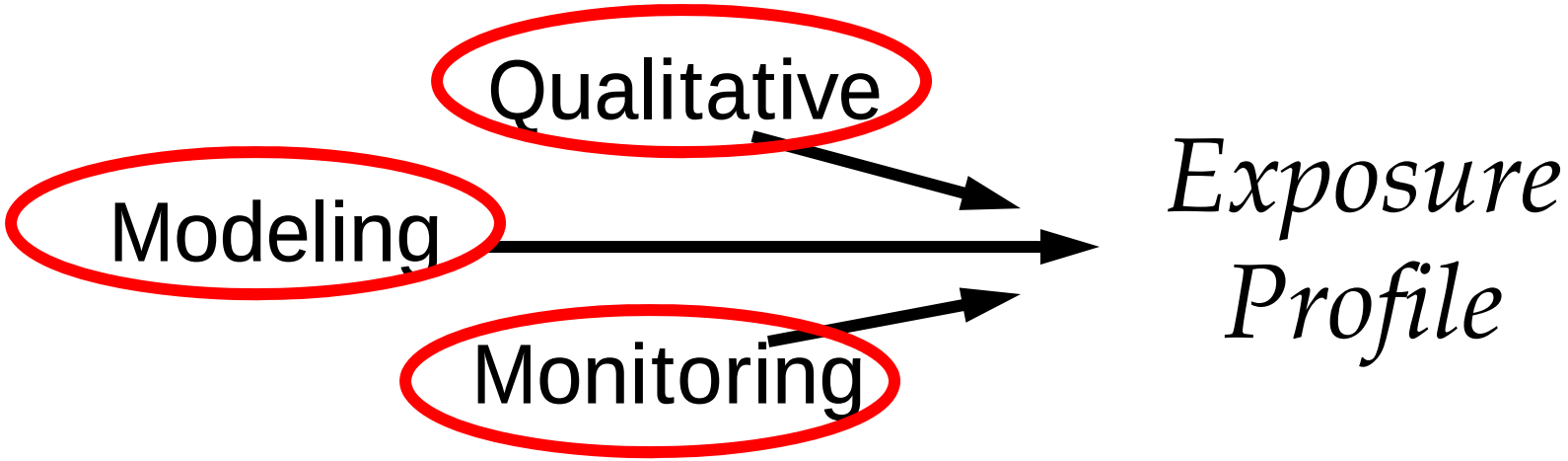

Add Monitoring Data . . . Validate Initial Judgments

Example: Exposure Estimate

Agent “X”

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35 to 65 mg/hour

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3.6 to 540 m^3/hour

Monitoring Results:

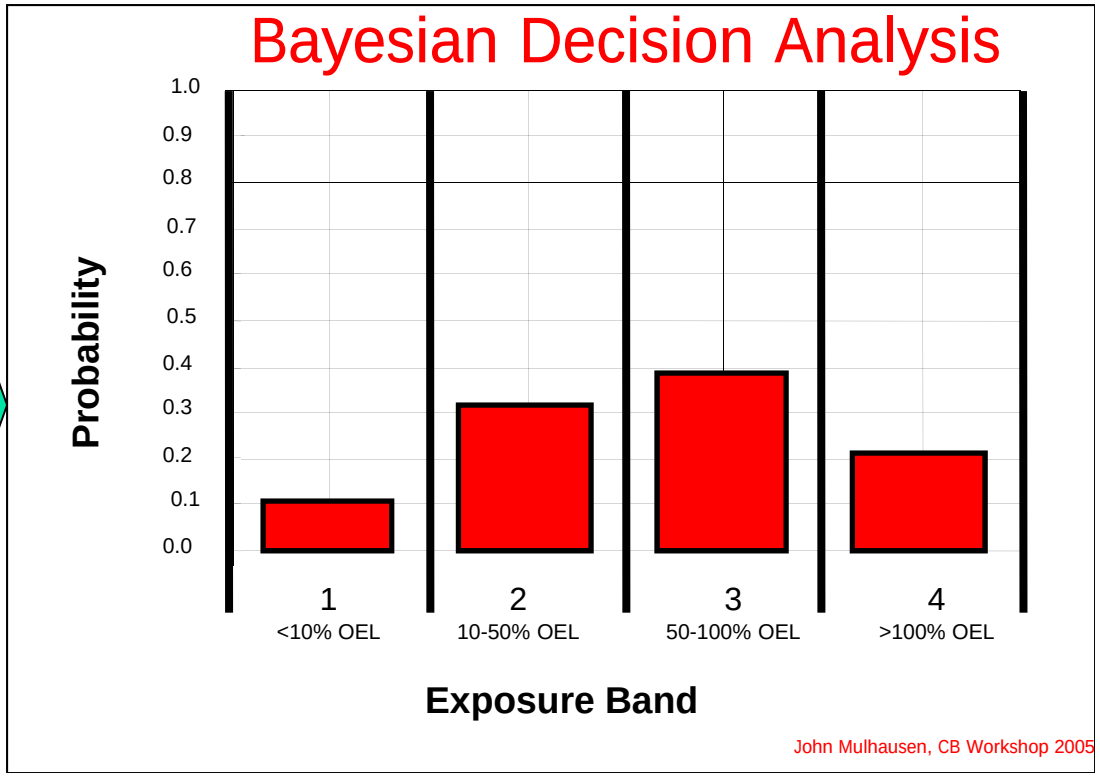
0.05 mg/M^3

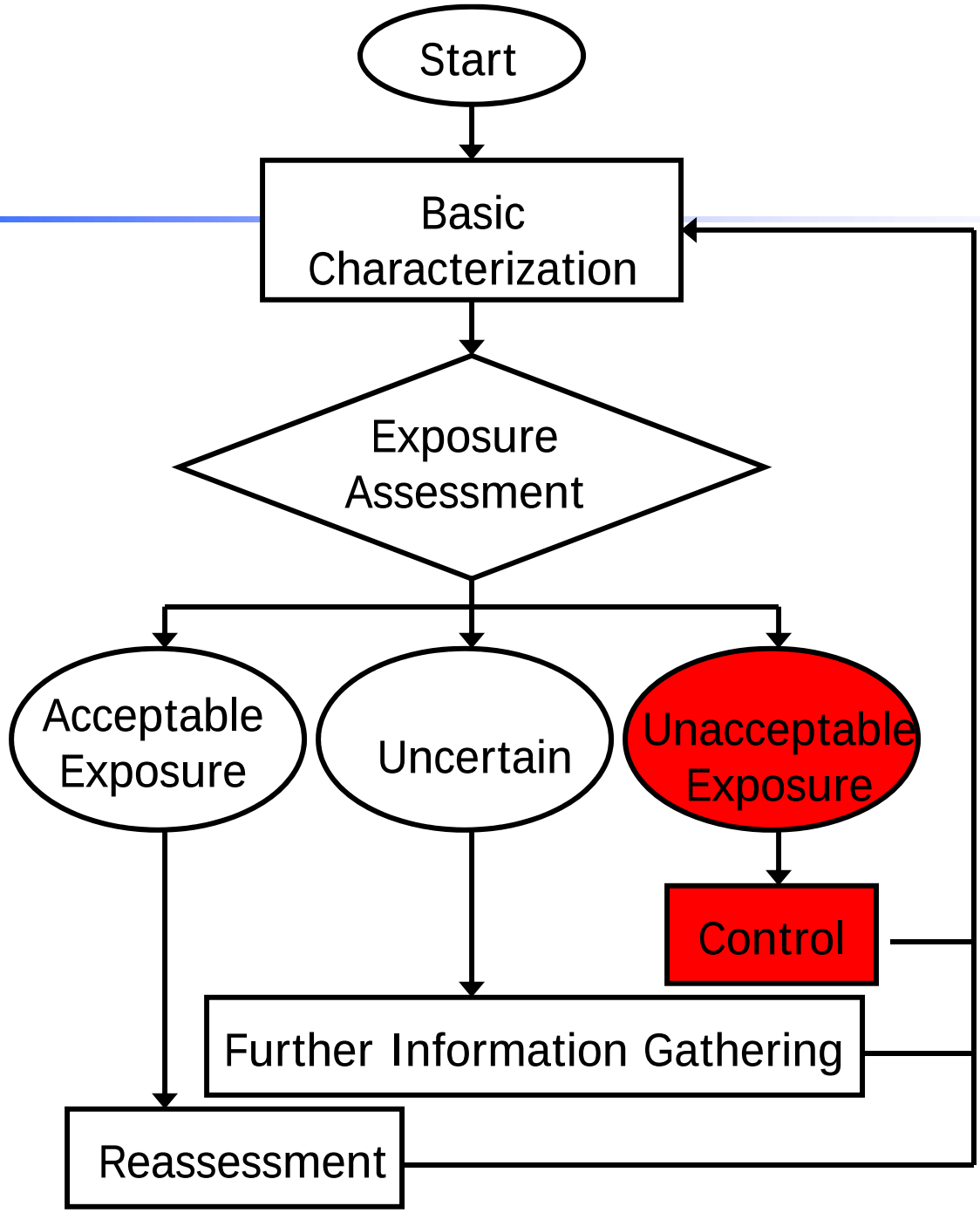
0.14 mg/M^3

0.21 mg/M^3

0.37 mg/M^3

0.78 mg/M^3

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Future use of Control Banding concepts

Integrate Control Banding concepts into a tiered, continuous improvement exposure risk assessment and management system.

- Working OELs are starting point for prioritized health-based OEL improvement
- Initial assessments characterized as Exposure Bands
- Validation of initial assessments based on Exposure Predictor Models and other assessment tools
- Verification of Control effectiveness in specific applications – leverage information to similar operations and to improve and validate models
- Continuous improvement and prioritization approach can focus down to specific operations, tasks, and individual work practices when needed