Reducing Workplace Exposure & Optimising the Physico-technical Performance of Potentially Harmful Trace Nutrients

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The Toxicity Tightrope

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My background

- Training – applied biologist
- Experience – premix, pharma and feed – regulatory – quality assurance
- Specialism – regulatory affairs – feed and veterinary
- Current focus - flavourings – regulatory environment/impact in nutrition/delivery systems
- Involvement with trace elements
  - 1990 onwards – investigated dust emissions cross-contamination etc. of micro-trace elements and pharmaceutical actives in the feed manufacturing process
  - Developed the concept of Propensity to Dust (of which more later)
  - Worked on EU registration projects for several trace element additives (including the focus today – selenium, cobalt, and iodine), veterinary medicines, and global registrations.

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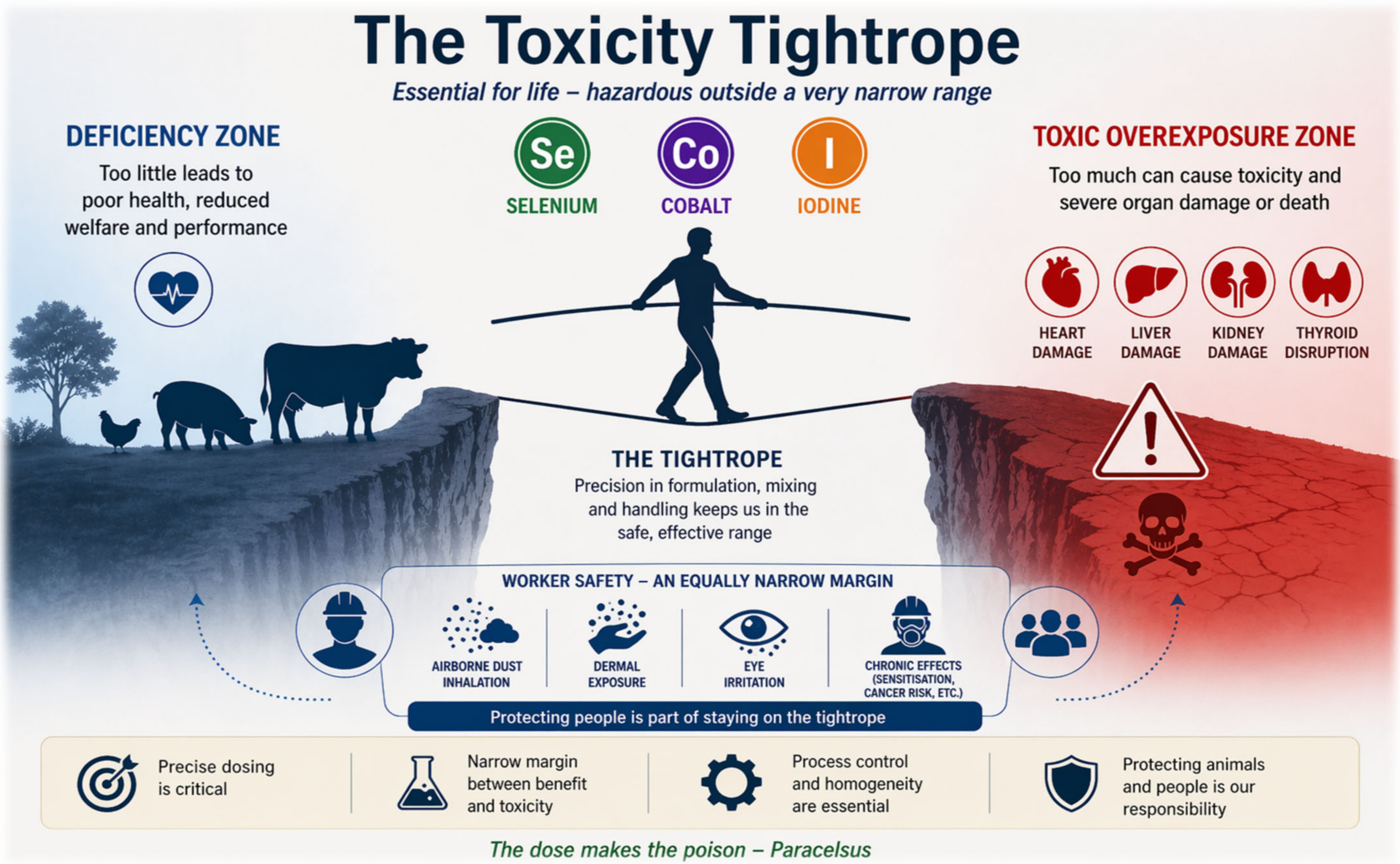
Scope

Part	Title	Part	Title
1	Framing the problem	7	Factors affecting dust generation
2	Defining Hazards	8	Measuring Dust
3	Risk Framework	9	Propensity to Dust.
4	Why exposure is the real problem	10	Homogeneity & Safety: A Trade-off
5	Physico-technical properties	11	Electrostaticity and HLB
6	Dust Generation	12	Cross-contamination

Part 1

Framing the problem – the “Toxicity Tightrope”



The Toxicity Tightrope
Essential for life – hazardous outside a very narrow range
DEFICIENCY ZONE
Too little leads to poor health, reduced welfare and performance
Se
SELENIUM
Co
COBALT
I
IODINE
TOXIC OVEREXPOSURE ZONE
Too much can cause toxicity and severe organ damage or death
HEART DAMAGE
LIVER DAMAGE
KIDNEY DAMAGE
THYROID DISRUPTION
THE TIGHTROPE
Precision in formulation, mixing and handling keeps us in the safe, effective range
WORKER SAFETY – AN EQUALLY NARROW MARGIN
AIRBORNE DUST INHALATION
DERMAL EXPOSURE
EYE IRRITATION
CHRONIC EFFECTS (SENSITISATION, CANCER RISK, ETC.)
Protecting people is part of staying on the tightrope
Precise dosing is critical
Narrow margin between benefit and toxicity
Process control and homogeneity are essential
Protecting animals and people is our responsibility
The dose makes the poison – Paracelsus

- Essential nutrients (and others)
- Hazardous outside a narrow range
- Cross-contaminating
- Harmful to non-target species
- Harmful to workers

Our Operational Reality

- Trace elements are handled at very low inclusion rates

- High dilution and multiple processing steps

- Airborne dust and particle behaviour influence exposure of:
  - Animals (dosing)
  - Workers (safety)

- Small deviations can have disproportionate consequences

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  - Workers (safety)
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This is not just a formulation problem
It is a systems problem

Hazard is fixed – exposure is systems driven

Part 2

Hazard Definition (Intrinsic Toxicity)

Our focus today

Element	Selenium	Cobalt	Iodine
Additive	Sodium Selenite	Cobalt II Carbonate	Calcium iodate anhydrous
Biological Role	Antioxidant systems	Vitamin B_{12} synthesis	Thyroid hormone synthesis
Risk driver	Intrinsic toxicity; dust behaviour	Inhalation exposure (occupational)	Process & dosing-driven behaviour (oxidising properties)
Key concern	Narrow safety margin; dust driven behaviour (OEL-driven risk)	Chronic inhalation exposure; dust driven behaviour (OEL-driven risk)	Homogeneity and variability; storage
Different elements ➔ different risk drivers ➔ different control strategies			

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Different elements ➔ different risk drivers ➔ different control strategies

RISK emerges from HOW they behave – not WHAT they are

Which affects the control strategies that must be used

Conditions of Use

Element	Additive	Species	Max. Limit (mg/kg)	
			Element (total)	Additive
Selenium (Se)	Sodium selenite (45 % Se)	All species	0.5	1.11
Cobalt (Co)	Cobalt carbonate (46 % Co)	Ruminants, Equidae, lagomorphs, rodents, herbivore reptiles & zoo mammals	1.0	2.17
Iodine (I)	Calcium iodate anhydrous (63 % I)	Equines	4	6.35
		Dairy ruminants & laying hens	5	7.94
		Fish	20	31.75
		Other species/categories	10	15.87

Toxicity Summary: Sodium Selenite

Source ECHA Database – Industry Classifications - unless otherwise stated

HAZARD CLASSIFICATION Regulation (EC) No 1272/2008	DANGER
WORKER SAFETY	
• Fatal if swallowed or inhaled (rat oral LD50 50 mg/kg bw) • Selenosis observed at ~0.02 mg/kg bw per day in humans • Chronic toxic dose human: ~ 3 mg Se per day (~0.03 mg/kg bw per day)	
• Causes skin irritation (reversible damage to skin)	
• Eye irritation (redness, pain, swelling for up to 21 days)	
• Skin sensitization (allergic contact dermatitis)	
• **Occupational Exposure Limit: dusts 0.1 mg/m^3 LTEL 8hr TWA ~ 3.5 mg in 8 hrs**	
ENVIRONMENTAL SAFETY	
• Very toxic to aquatic life (acute) (<1 mg/L; 96hr fish; 48 hr crustacea)	
• Toxic to aquatic life with long-lasting effects (>1 to <10 mg/L)	

Toxicity Summary: Sodium Selenite Source ECHA Database – Industry Classifications - unless otherwise stated

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ENVIRONMENTAL SAFETY

- Very toxic to aquatic life (acute) (<1 mg/L; 96hr fish; 48 hr crustacea)
- Toxic to aquatic life with long-lasting effects (>1 to <10 mg/L)

Toxicity Summary: Cobalt (II) Carbonate Source ECHA Database – Industry Classifications – unless stated otherwise

HAZARD CLASSIFICATION Regulation (EC) No 1272/2008	**DANGER**	
WORKPLACE		
May cause cancer by inhalation (known to occur in humans)		
Suspected of causing genetic defects (positive evidence in mammalian studies)		
May damage fertility; may damage the unborn child (presumed for humans based on animal studies)		
Harmful if swallowed (acute toxicity > 300 < 2000 mg/kg bw)		
May cause allergy or asthma symptoms or breathing difficulties if inhaled (low to moderate frequency shown in humans)		
May cause an allergic skin reaction (evidence in humans or positive results in animal tests)		
Occupational Exposure Limit: dusts 0.1 mg/m^3 LTEL 8hr TWA **Proposed EU OEL: 10 $\mu g/m^3$ inhalable / 2.5 $\mu g/m^3$ respirable**		
ENVIRONMENT		
Very toxic to aquatic life (acute) (<1 mg/L; 96hr fish; 48 hr crustacea)		
Very toxic to aquatic life with long-lasting effects (observed effects at >0.01 mg/L)		

Toxicity Summary: Calcium iodate anhydrous Source ECHA Database – Industry Classifications

HAZARD CLASSIFICATION Regulation (EC) No 1272/2008	**DANGER**
Oxidising solids (may intensify or cause fire)	
Skin Irritation (reversible moderate inflammation, erythema, or edema)	
Eye Irritation (significant but reversible eye irritation)	
Respiratory tract Specific target organ toxicity – single exposure (transient non-lethal, respiratory tract irritation)	
No OEL – minimise exposure with preventive measures	

Part 3

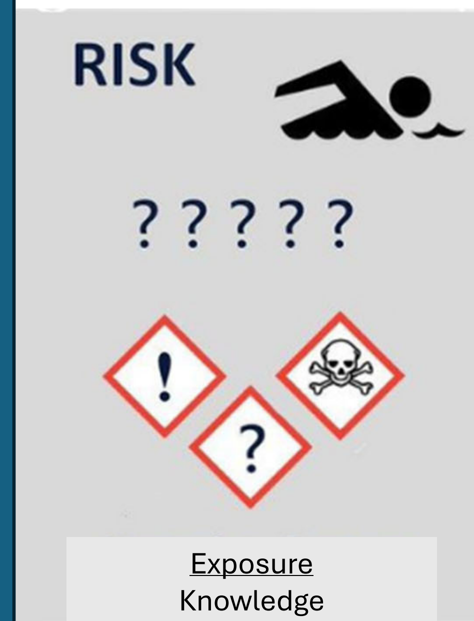
Risk Framework: Hazard x Exposure

Hazard Alone Does Not Define Risk

Image from KEN Institute

Hazard Alone Does Not Define Risk

Image from KEN Institute



Hazard Alone Does Not Define Risk – Exposure Does

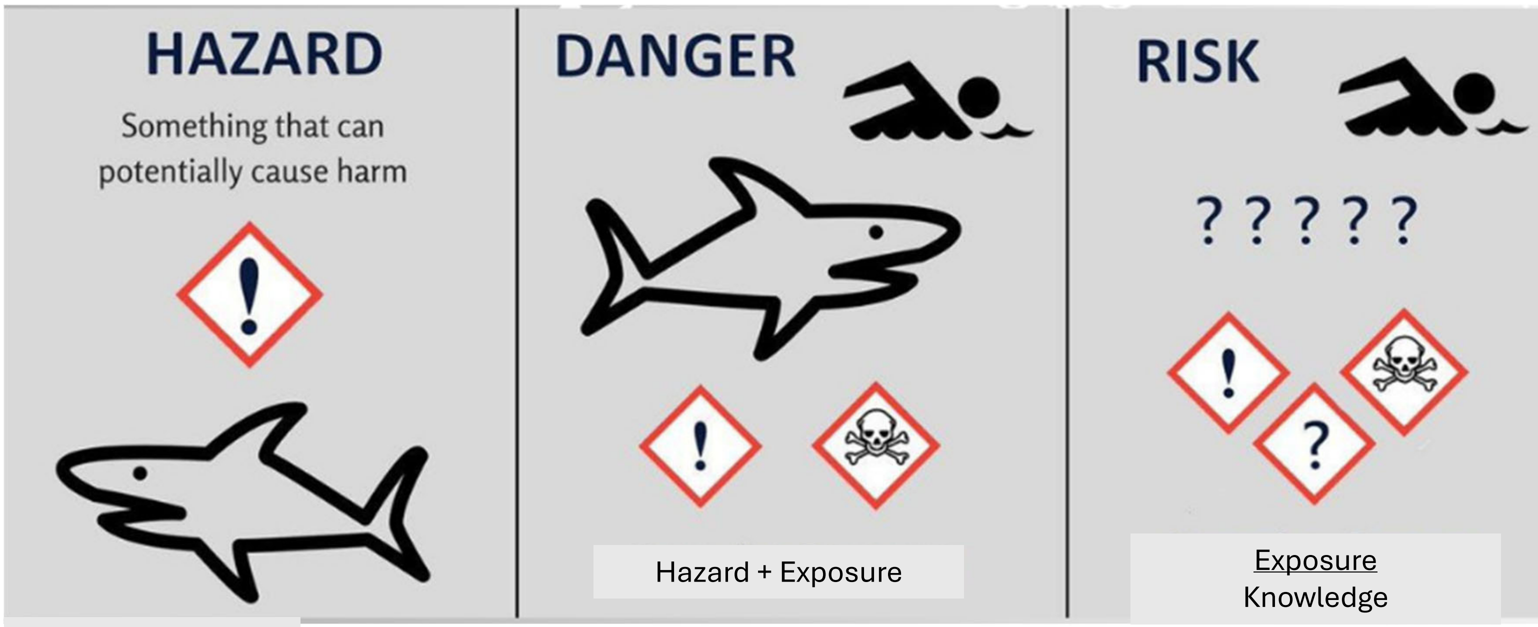


Image from KEN Institute

- **Different elements ➔ different risk drivers ➔ different control strategies**
- Lower toxicity ≠ Lower risk if exposure increases

Part 4

Why exposure is the real problem in feed manufacturing systems

What determines exposure in feed manufacturing processes?

Micro trace elements are uniquely challenging

Very low inclusion levels → High dilution rates

Handling, mixing, conveying → Airborne potential

Workplace variability → Exposure

Micro trace elements are uniquely challenging

- Very low inclusion levels → High dilution rates, Uniformity
- Handling, mixing, conveying → Airborne potential, Unpredictable
- Workplace variability → Exposure levels unpredictable

Can we manage what we cannot reliably predict?

Part 5

Physico-Technical Properties

From Properties to Exposure – A Three-Level System

LEVEL	MEANING
Material Properties	What particles *are*
Particle Behaviour	What particles *do*
System Outcomes	What the system *produces*

From Properties to Exposure – A Three-Level System

LEVEL	MEANING
Material Properties	What particles *are*
Particle Behaviour	What particles *do*
System Outcomes	What the system *produces*

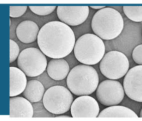
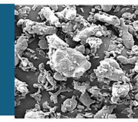
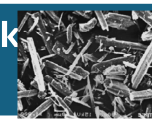
Risk emerges when properties drive behaviour within a system

Physico-Technical Properties

Property	Character
Particle size	- Micro - Macro
Particle shape	- Sphere - Irregular polygon - Rod/needle
Bulk density	- < matrix - = matrix - > matrix
Surface Properties • Hydro-Lipophile Balance – HLB • Electrostatic properties	- Fat loving - Moisture loving - Neutral
	- Chargeable - Insulative - Dissipative - Neutral

Particle Properties Drive Behaviour and Risk

Shape

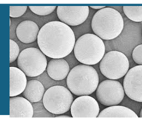
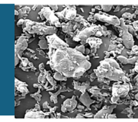
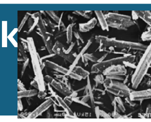
Spherical 	Irregular Friable 	Needle-lik Fibrous 
➔Low inter-particle interaction ➔Low friction/breakage	➔High inter-particle interaction ➔High fracture/fines	➔Interlocking behaviour ➔Poor flowability ➔ Airborne persistence
Shape determines how particles interact and break		

Relative Density

< matrix	= Matrix	> Matrix
➔Airborne / entrainable ➔Highly Mobile	➔Stable ➔Well-dispersed	➔Settling/deposition ➔Segregating
Relative density determines how particles move and segregate		

Particle Properties Drive Behaviour and Risk

Shape

Spherical 	Irregular Friable 	Needle-lik Fibrous 
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Relative density determines how particles move and segregate		

Shape controls interaction – Density controls movement
Together these properties drive dust formation, segregation and exposure

Intrinsic properties of materials

- Define how particles can *behave*
- Do not define system *outcomes*

A materials intrinsic properties drives its behaviour

Why These Matter

Characteristics	RISK DRIVERS FOR:			
	Dust emissions	Homogeneity issues	Segregation	Cross-contamination
Particle Size	5★	5★	5★	5★
Particle Shape	3★	5★	5★	1★
Bulk Density	5★	5★	5★	5★
Polarity (HLB)	2★	5★	5★	5★
Electrostaticity	5★	3★	3★	5★

Part 6

Dust Generation – Theory to Reality

What is Dust?

Solid ➔ Force ➔ Particle Release ➔ Airborne Behaviour

Key (Crucial) Principle

Dust Generation is a function (f) of:

f = (Material Properties X Applied Forces)

Hierarchy of Control – Does it work for trace elements?

Standard Hierarchy	Reality in Feed Systems
1. Elimination	❌ Not possible ➔ Nutritionally essential
2. Substitution	⚠️ Limited opportunity ➔ Often same hazard in different form
3. Engineering Controls	⚠️ Partial ➔ May remove active (losses to LEV)
4. Administrative Controls	⚠️ Variable ➔ Human dependent
5. Personal Protective Equipment	⚠️ Last resort ➔ Does not address root cause

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Traditional control hierarchies

Do not address the root cause of particle behaviour

Part 7

Factors Affecting Dust Emissions

Key (Crucial) Principle

Dust Generation is a function (f) of:

f = (Material Properties X Applied Forces)

f = (Material Properties X Process Factors)

Materials

Particle size distribution and robustness
→ Fine particles increase dust

Particle shape
→ Irregular / friable particles increase dust

Cohesiveness
→ Affects dust emissions, mixability, cross-contamination

Moisture content
→ Can increase binding (reduce dust) but variable

Polarity (HLB)
→ Affects interaction with feed matrix

Electrostatic behaviour
→ Influences adhesion and dispersion

Processes

Handling energy
→ Mixing, conveying, discharge

Degree of dilution
→ Disrupts binding forces

Particle fracture / attrition
→ Generates fines

Formulation effects
→ Mixtures of fine + coarse increase dust

Environmental conditions
→ Humidity, airflow

Dust Emissions Are:

SYSTEM DEPENDANT AND NON-LINEAR

NOT PREDICTABLE

Part 8

Measurement of Dust Emissions – A “Benchmark” for assisting Prediction

Predicting Dust Emissions

1. **Rate of Dust Generation** = $f\left(\dfrac{\text{Separation Forces}}{\text{Interparticulate Binding Forces}}\right)$

2. **Rate of Dust Generation for particles of size *i*** = $\left(\text{Fraction of particles of size } i \text{ in test material}\right) f\left(\dfrac{\text{Separation Forces}}{\text{Interparticulate Binding Forces}}\right)$

Where "*f*" is a factor that is material AND situation specific

Foundational Principle

We CANNOT predict dust

We CAN compare materials

What can we control?

- Variability between each individual workplace across the premix and feed industry?
  - Impossible to control (standardise)

- The characteristics of the materials that the industry handles?
  - Possible by supplier selection
  - But how do we choose?
  - **What benchmark(s) can we use to compare sources?**
  - **We need a standardised test**

Laboratory Test Methods Must:

- Simulate realistic handling conditions
- Accommodate a wide range of physico-technical characteristics
- Be Repeatable
- Be reproducible
- Assist in the application of a constant factor – $f(x)$

Dust generation = $f(x)$ (material properties x applied forces)

Three Basic Types of Test Methods

Technique	**Application**
Drop Method	Limited application
Fluidisation	
Rotational	Multiple applications
There is a need for a standardised method	

Feed Specific Method – Rotational

The Stauber-Heubach Test

Heubach Dustmeter – Type II
(DIN 55992) Configuration

- Developed for feed additives (1987) (DIN 55992)
- Regulatory Requirement (1831/2003 – 429/2008)
- Strong link to workplace risk assessment philosophy (crucially OELs)

Comparing Materials: Benchmarking

- Measures comparative dustiness of materials
- Strong link to workplace risk assessment philosophy (crucially OELs)

Foundational Principle

We can measure 'behaviour'

We can compare materials

We cannot predict behaviour

Foundational Principle

We can measure ‘behaviour’

We can compare materials

We cannot predict behaviour

Unless we modify material properties

Dust Emissions Feed Additives – SH-Test

Additive	Average Particle size (µm)	Total Dust (mg)	Total Dust (mg/m^3)
Na_2SeO_3	~43	19.5	97.5
$CoCO_3$	<6	322.9	1614.5
$CaI(O_3)_2$	~30	69.5	321.5

Dust Emissions Feed Additives – SH-Test

Additive	Average Particle size (µm)	Total Dust (mg)	Total Dust (mg/m³)	OEL (LTEL 8hr TWA)
Na_2SeO_3	~43	19.5	97.5	**0.1 mg/m³**
$CoCO_3$	<6	322.9	1614.5	**0.1 mg/m³ (2.5 – 10 µg proposed)**
$CaI(O_3)_2$	~30	69.5	321.5	N/A

Part 9

Propensity to Dust

Do dust clouds reflect the original material?

Ingredient	Premix (% w/w)	Dust (% w/w)
Cobalt carbonate	0.07	0.3
Iron carbonate	8.3	8.6
Manganese oxide	3.02	2.3
Copper sulphate	5.6	0.6
Sodium selenite	0.01	0.4
Zinc oxide	7.62	12.6
Calcium carbonate	75.4	75.8

SH-Test

- Broiler Premix
- 50g Sample
- 4/L per min.
- 20 min.
- Assays by AA & ICP-MS

Do dust clouds reflect the original material?

S-H Test Results –Broiler Mineral Premix		
Ingredient	**Premix (% w/w)**	**Dust (% w/w)**
Cobalt carbonate	0.07	0.3
Iron carbonate	8.3	8.6
Manganese oxide	3.02	2.3
Copper sulphate	5.6	0.6
Sodium selenite	0.01	0.4
Zinc oxide	7.62	12.6
Calcium carbonate	75.4	75.8

4 x Enrichment

40 x Enrichment

Why this Matters

Exposure = <u>Propensity to Dust </u>x Dust

Propensity to Dust (PD)

Propensity to Dust (PD) of ingredient x is:

$$PD = \frac{C_{dust,x}}{C_{bulk,x}}$$

$C_{dust,x}$ = concentration of ingredient x in the dust

$C_{bulk,x}$ = concentration of ingredient x in the bulk sample

Interpretation of PD results

PD = 1 → representative

PD > 1 → enrichment in dust

PD < 1 → depletion

Exposure is driven by $\mathbf{PD}$ and NOT inclusion rate

Total Dustiness (mg/kg)

$$D_{total} = \frac{m_{dust}}{m_{bulk}} \times 10^6$$

- $\boldsymbol{D_{total}}$: Total dustiness expressed in **mg/kg**.
- $\boldsymbol{m_{dust}}$: The mass of dust collected on the filter, usually measured in **grams (g)** or **milligrams (mg)**.
- $\boldsymbol{m_{bulk}}$: The mass of the original sample (y) placed in the Stauber-Heubach drum, typically **100 g**.
- $\boldsymbol{10^6}$: A conversion factor to ensure the final result is in milligrams of dust per kilogram of bulk material.

PD and Occupational Exposure Limits (OELs)

Ingredient	PD	Dust as mg/m³ In the S-H test	OEL (mg/m³ 8 hr. TWA)
Cobalt carbonate	4.29	1.5	**0.1** **Proposed: 0.01 inhalable / 0.0025 respirable**
Iron carbonate	1.04	43	N/A
manganese oxide	0.76	11.5	0.1
Copper sulphate	0.11	3	N/A
Sodium selenite	40.00	2	**0.1**
Zinc oxide	1.65	63	N/A
Calcium carbonate	1.01	379	N/A

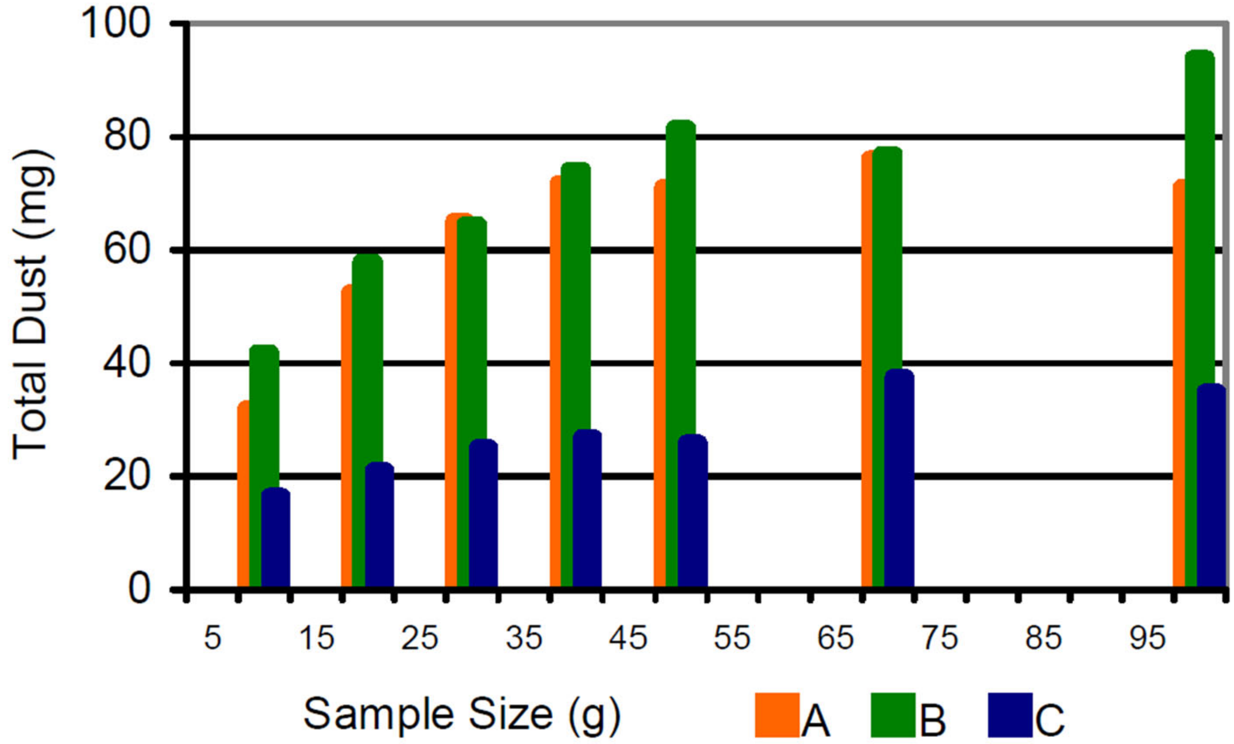
What happens with further dilution?

Premixture to feed dilution		
Measurement	**Premixture** →	**Feed**
Total Dust (SH-Test filter)	83.5 mg	8 mg
Sodium selenite content of dust (%)	0.06 % (0.05 mg; 0.3 mg/m3)	0.09 % (0.007 mg; 0.144 mg/m3)
PD sodium selenite	6	9

Two different premixtures (Manganous oxide; Mn OEL = 50ug – 200ug)		
Measurement	**Premixture – 3.87 % MnO**	**Premixture 1.6 % MnO**
MnO at SH-filter	227 ug	230 ug

Dilution has AMPLIFIED the potential risk

Effects of Sample Size in S-H test



Propensity to Dust Changes Everything

- Dust composition ≠ bulk composition
- Exposure cannot be predicted from:
  - Inclusion rate
  - Total dust alone
- PD varies:
  - By material
  - By process
  - By dilution
- Workplace Exposure is driven by particle behaviour, and not formulation alone

Working assumption ….

- Linear relationship between formulation and dust
- Dust Composition = Bulk Composition

Working assumption …. Is false!

- Linear relationship between formulation and dust ❌
- Dust Composition ≠ Bulk Composition
- Actual: PD driven

Exposure = PD x Dust

Summary

1. Dust exists
2. Dust is variable (system effects)
3. Dust is **not representative** (not linear)
4. PD explains why
5. Dilution can amplify the problem (enrichment)

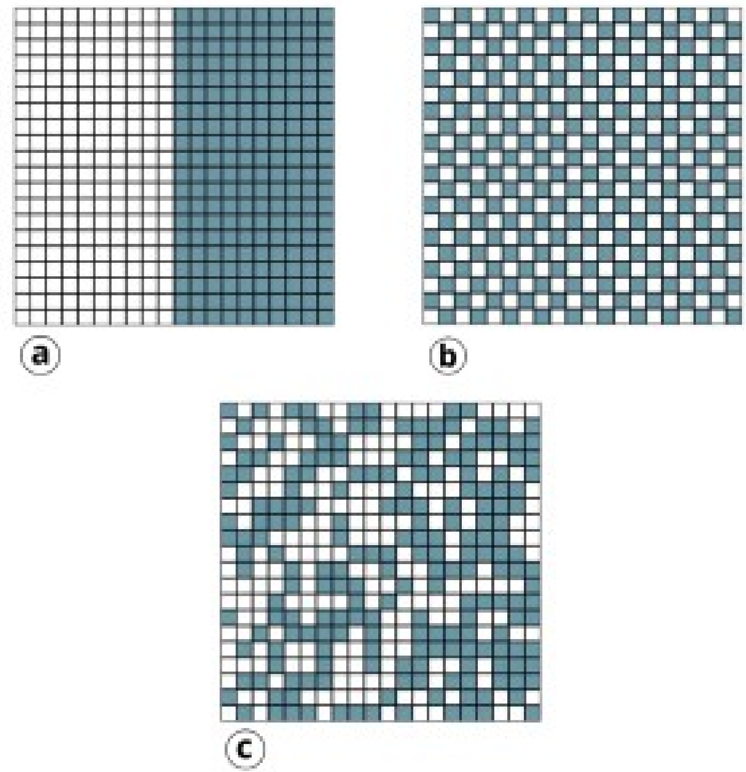
risk cannot be inferred from formulation alone

Part 10

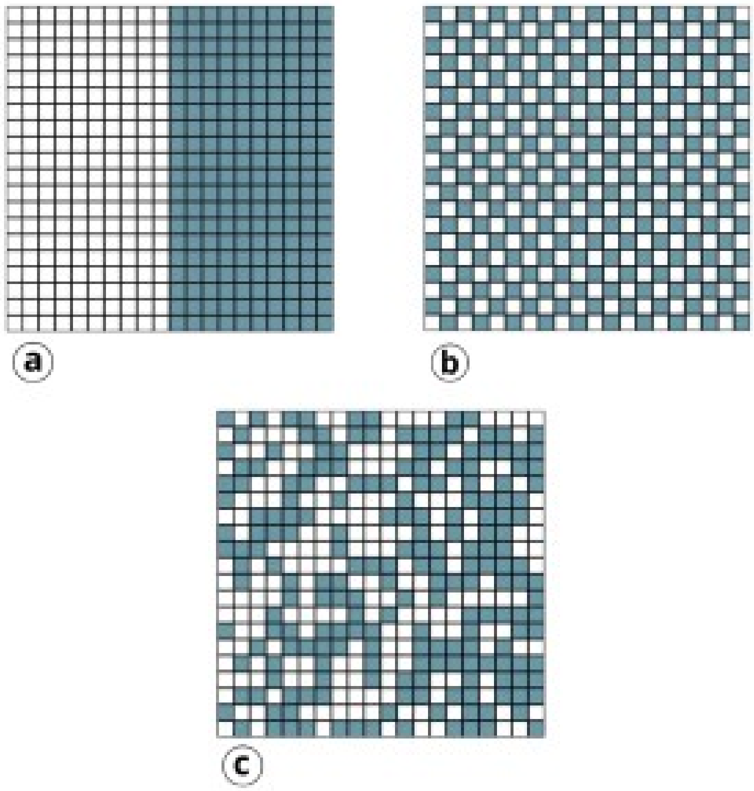
Homogeneity vs. Safety: Trade Off?

Homogeneity in Powder Blends

- Uniform distribution of particles
- Critical at trace levels
- Small deviations ➔ big effects?



Scale of Scrutiny



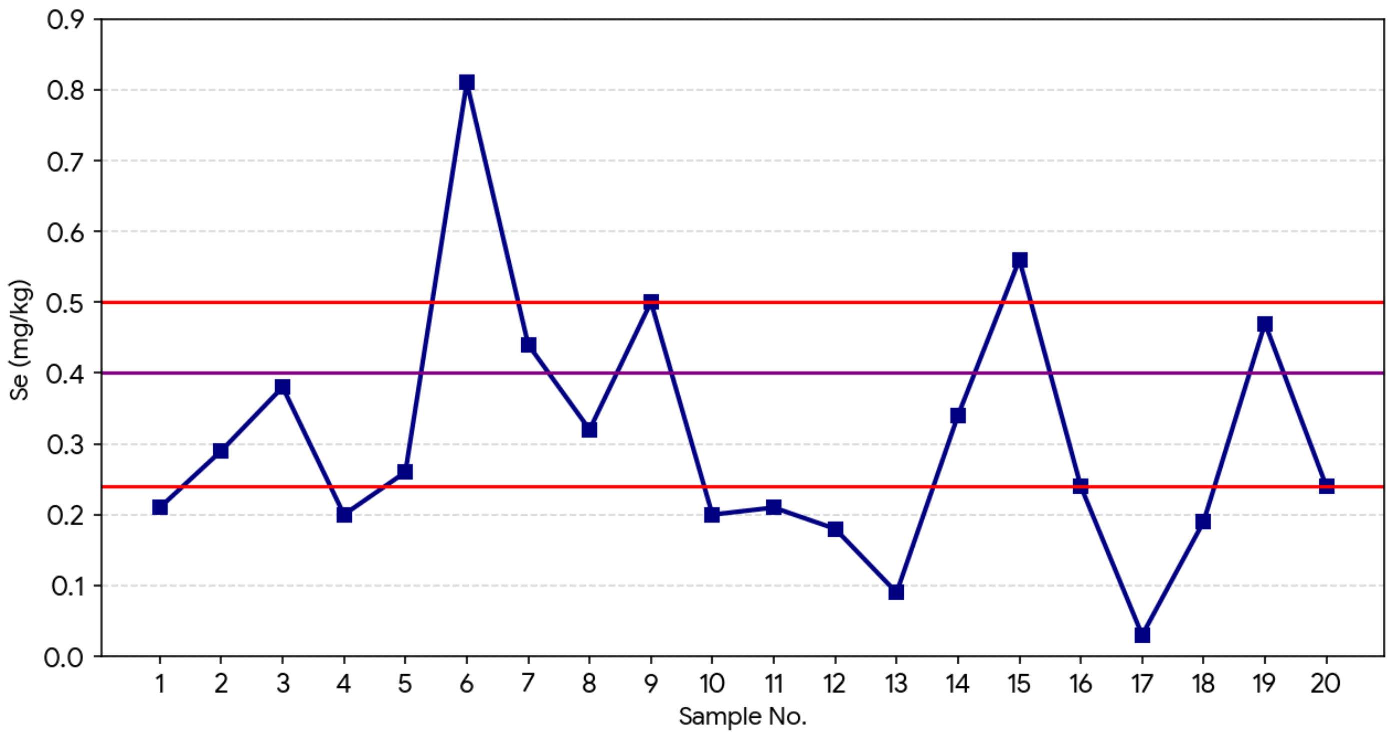
- Which of these is uniformly distributed?
- It depends on the scale of scrutiny ....
- A material can appear homogeneous at one scale and heterogeneous at another

At trace levels, small mixing errors could become larger biological problems

Sodium selenite data – feed mixing test

Parameters		
Target selenium assay (mg/kg)	0.4	
Mean assay (mg/kg)	0.308	
Minimum assay (mg/kg)	0.03	**? efficacy**
Maximum assay	0.81	**> 0.5 (max. level in complete feed)**
St. Deviation (SD)	0.186	
Coefficient of variation (CV%)	59.38	**> 10-20 (acceptable range for feed)**
Process Capability(mean ± 3 SD)	0 – 0.87	

Legal Technical Limits (EU Regulation 767/2009)



Limits: 40 % of declared if under (0.24 mg/kg)

Max. allowed level (total)

Label declaration (target)

Maximum allowed lower limit

Formulation modification

Parameters	Sodium selenite	Optimised (0.45 % Se)
Target selenium assay (mg/kg)	0.4	
Mean assay (mg/kg)	0.308	0.315
Minimum assay (mg/kg)	0.03	0.22
Maximum assay	0.81	0.41
St. Deviation (SD)	0.186	0.065
Coefficient of variation (CV%)	59	20
Process Capability(mean ± 3 SD)	0 – 0.87	0.012 – 0.509

Particle size

- Optimised for feed

HLB

- Neutral

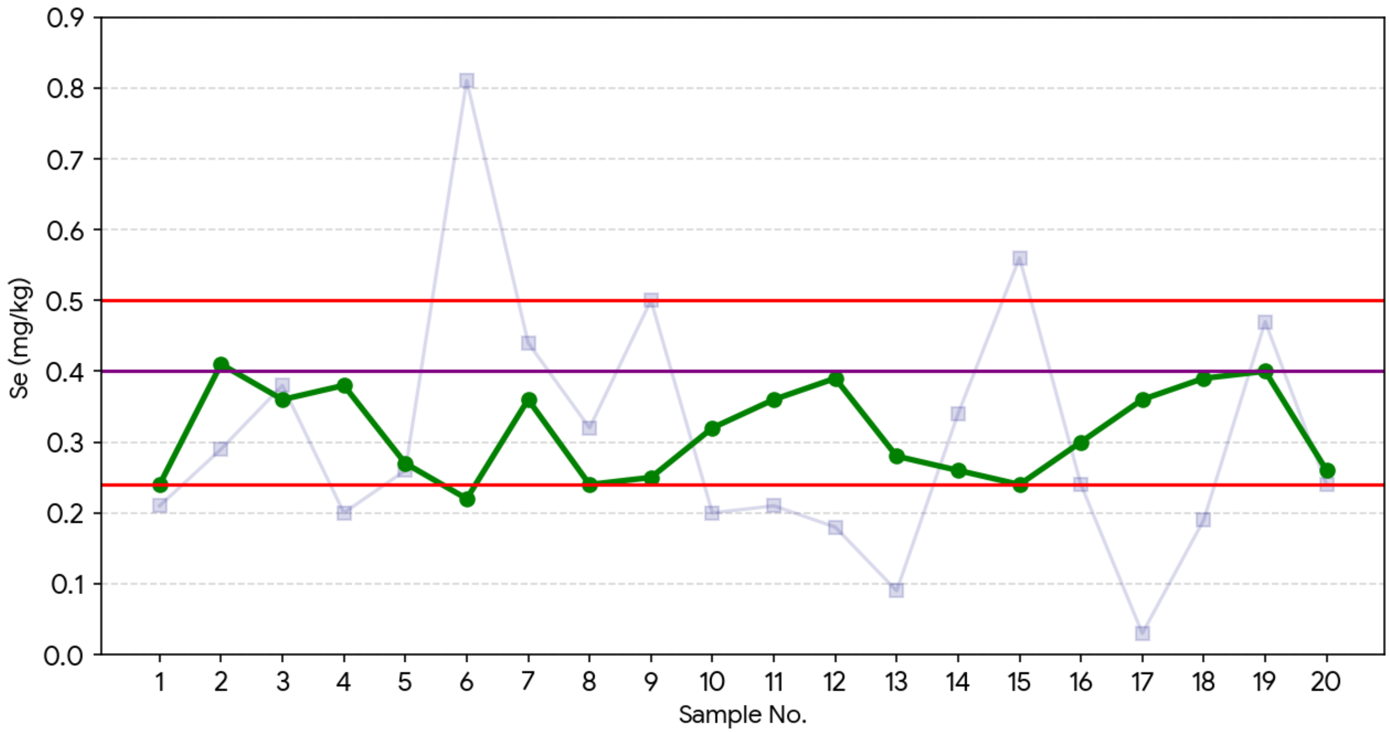
Dust emissions:

- < 2 mg SH-Test

Electrostaticity

- Dissipative

Modified properties



Particle size

➢ Optimised for feed

HLB

➢ Neutral

Dust emissions:

➢ < 2 mg SH-Test

Electrostaticity

➢ Dissipative

The Trade-off

Fine Particles

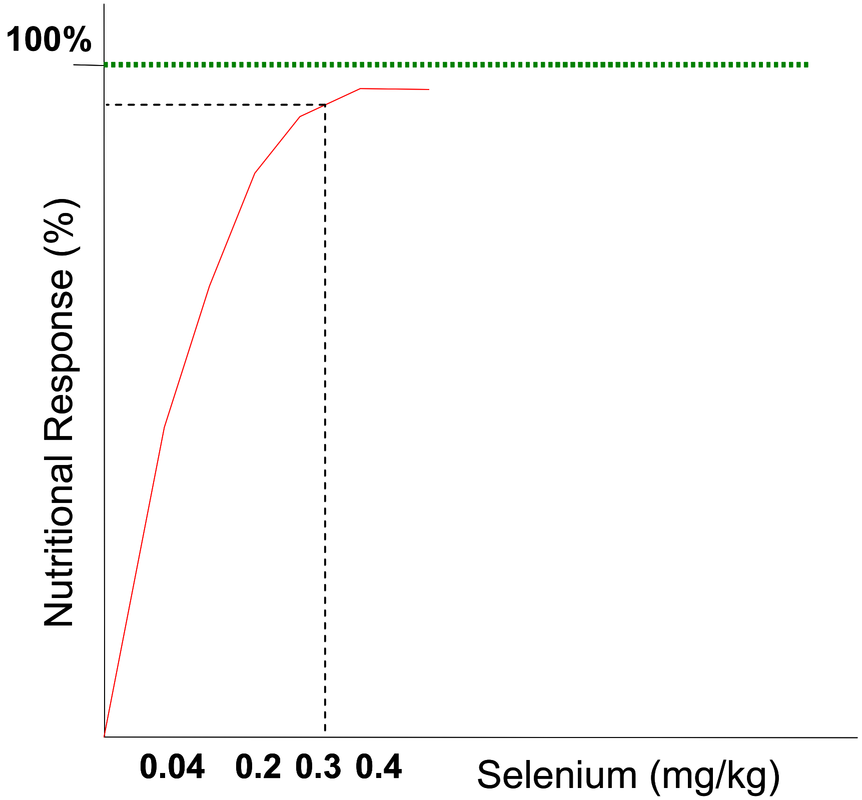
- Better homogeneity **(provided they disperse)**
- Higher risks
  - Dust exposure
  - Cross-contamination

Coarse Particles

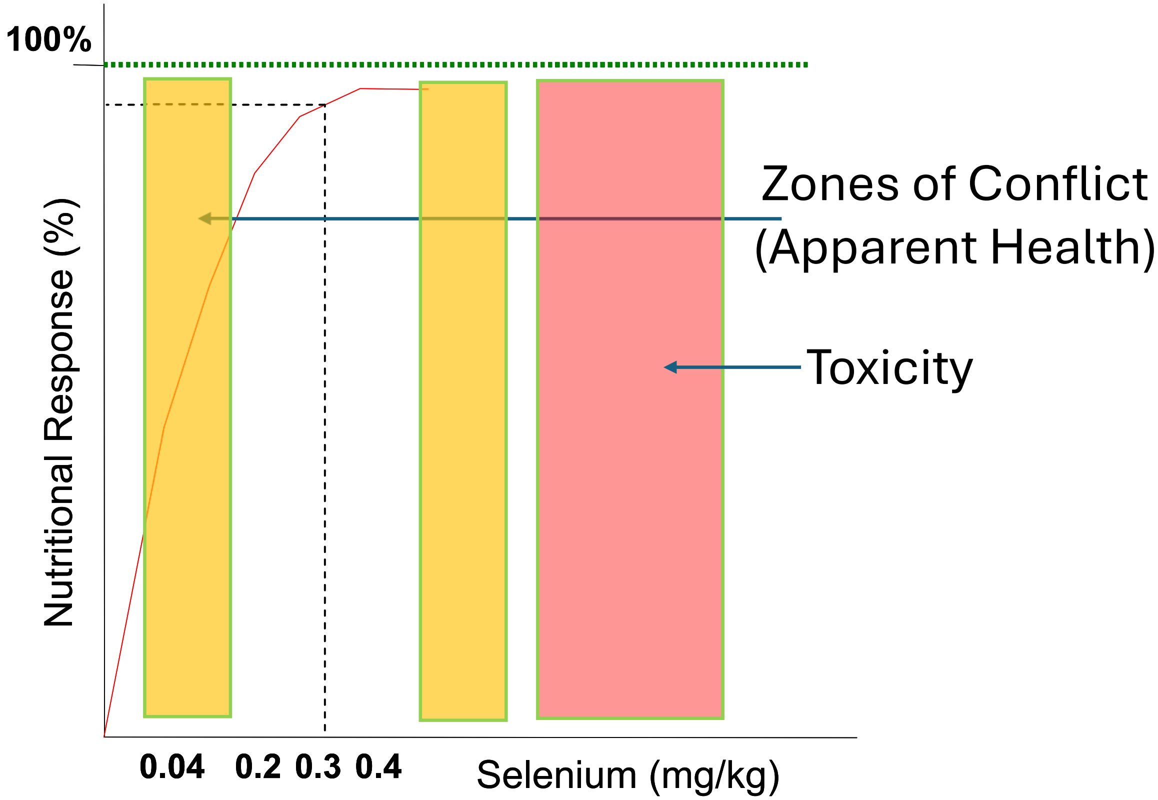
- Lower risks
  - Dust
  - Cross-contamination
- Increased potential for segregation

The properties that improve mixing can increase exposure to risks

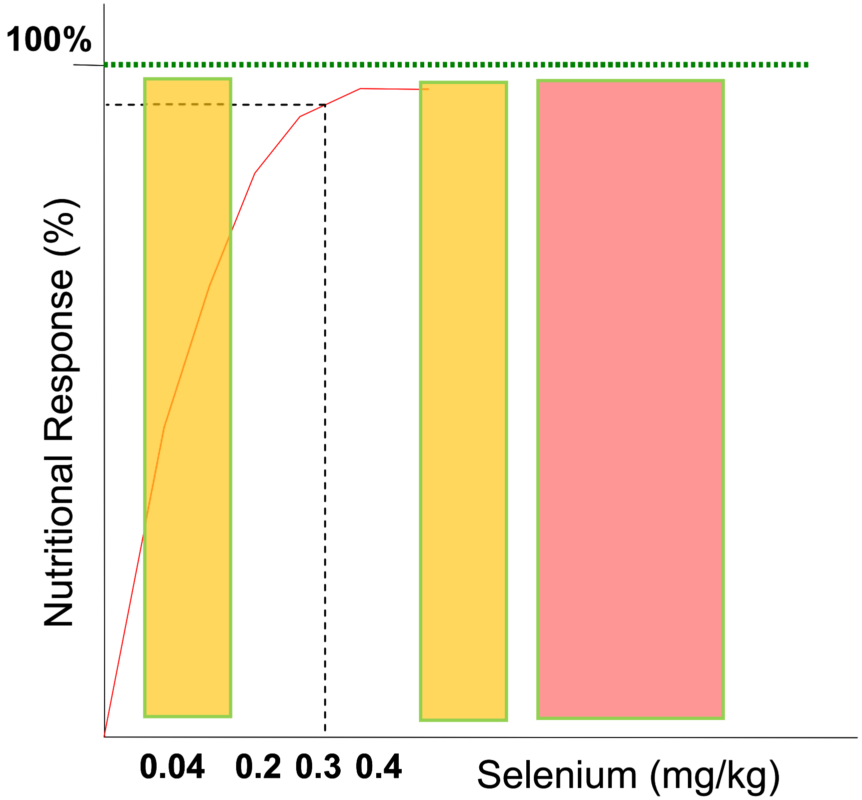
Implications extend beyond safety – to efficacy

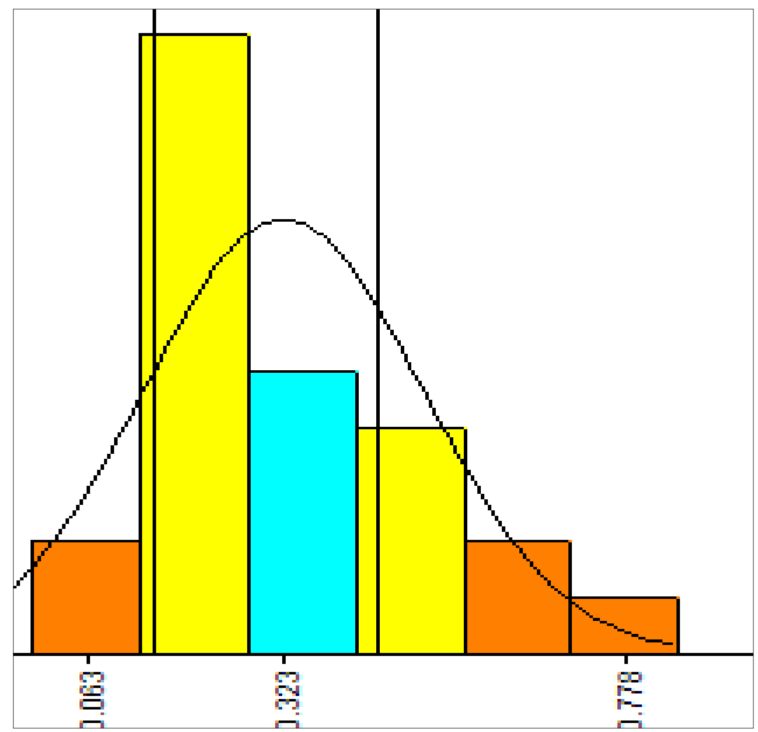


Implications extend beyond safety – to efficacy



Implications extend beyond safety – to efficacy





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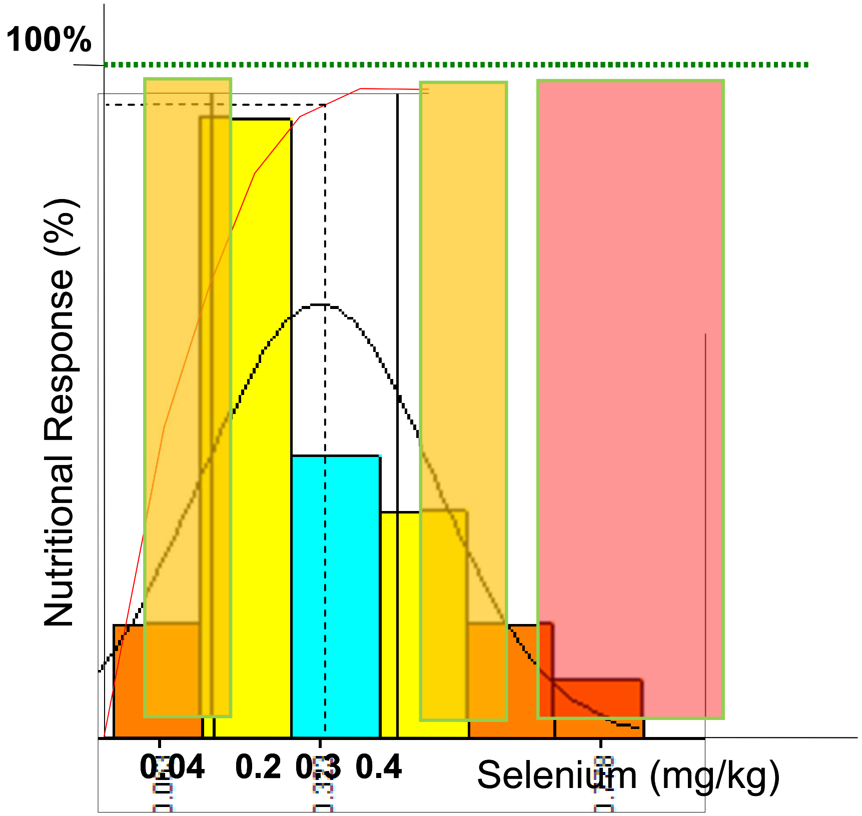
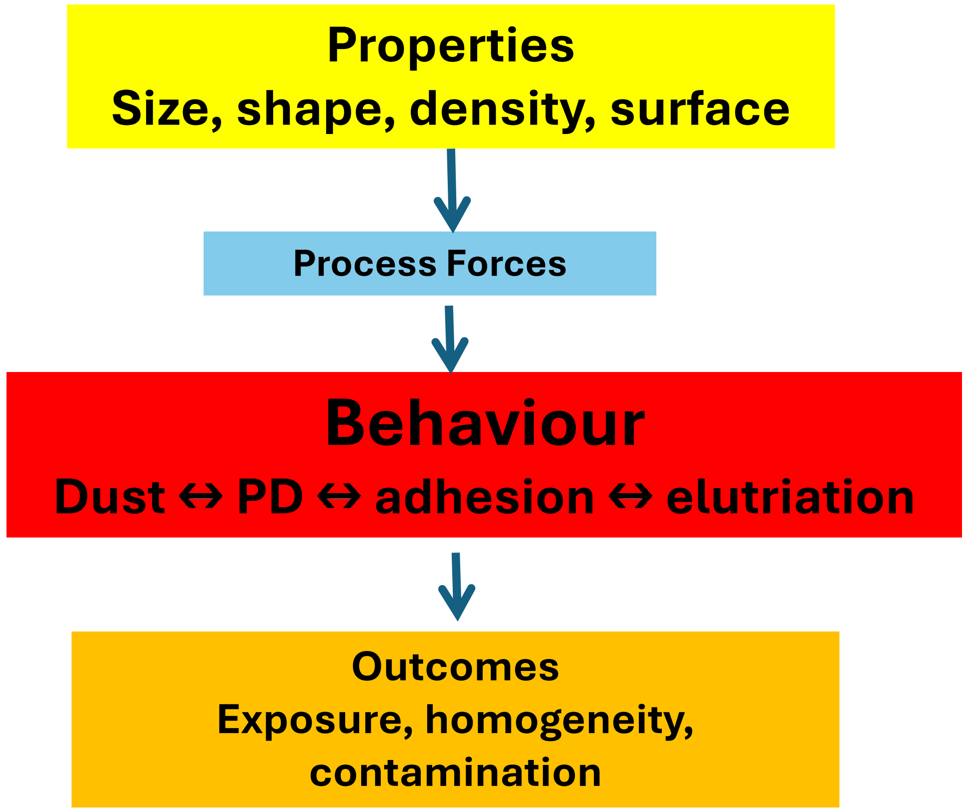


From particle to exposure: The system behind risk



Exposure is an emergent property of behaviour

Part 11

Surface properties, adhesion and cross contamination

Surface Properties (with Particle Size) Drive Cross-Contamination

- **Electrostaticity**
  - Charge generation during handling
  - Attraction / repulsion between particles

- **HLB (Hydro-Lipophile Balance)**
  - Surface affinity (moisture vs fat)
  - Interaction with feed matrix

How?

- Electrostatic forces → particle attraction
- HLB → affinity for surfaces (moisture/fat phases)
- Combined effect:
  - Adhesion to equipment
  - Cohesion between particles

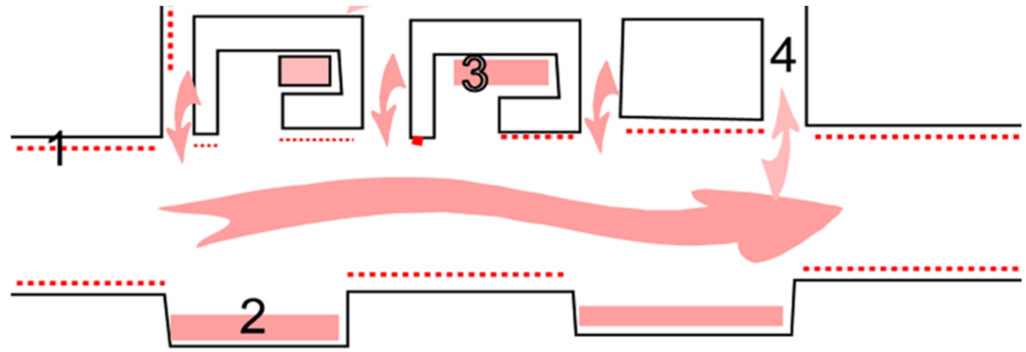
The same mechanisms that drive dust – also drive contamination

Part 12

Cross-contamination

Cross-contamination: A System Effect

- Deposition on surfaces
- Build-up (reservoir formation)
- Release during subsequent processing

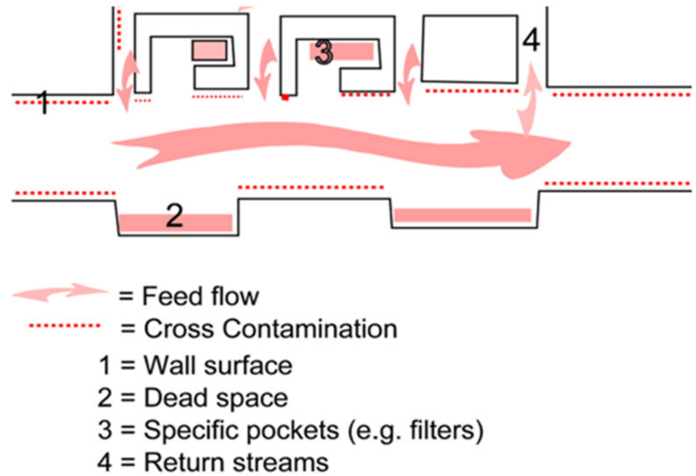


After Beumer; TNO, Wageningen

= Feed flow
= Cross Contamination
1 = Wall surface
2 = Dead space
3 = Specific pockets (e.g. filters)
4 = Return streams

Cross-contamination: A System Effect

- Deposition on surfaces
- Build-up (reservoir formation)
- Release during subsequent processing



After Beumer; TNO, Wageningen

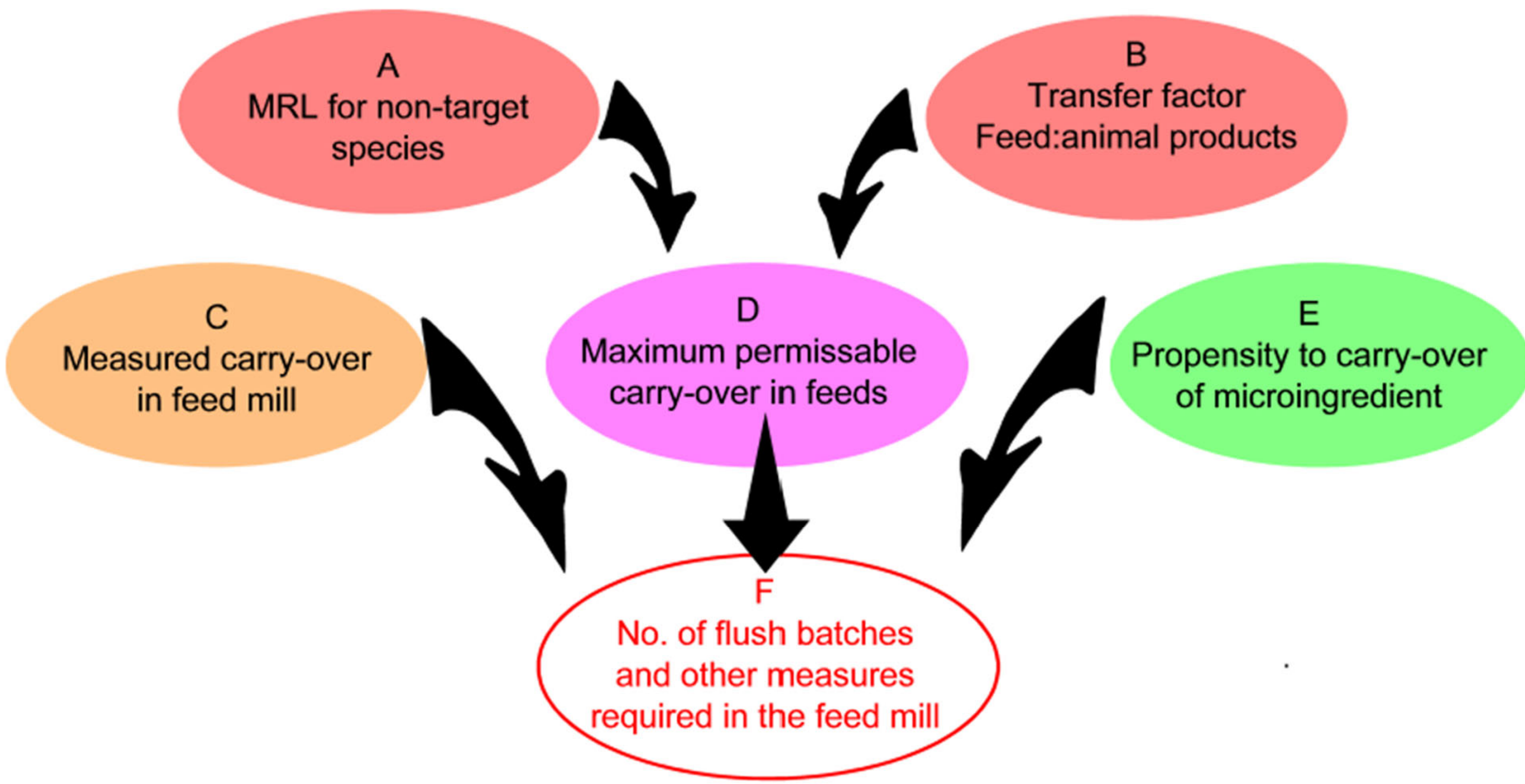
Systems store and redistribute contaminants over time

Adhesion is driven by electrostaticity and surface affinity effects

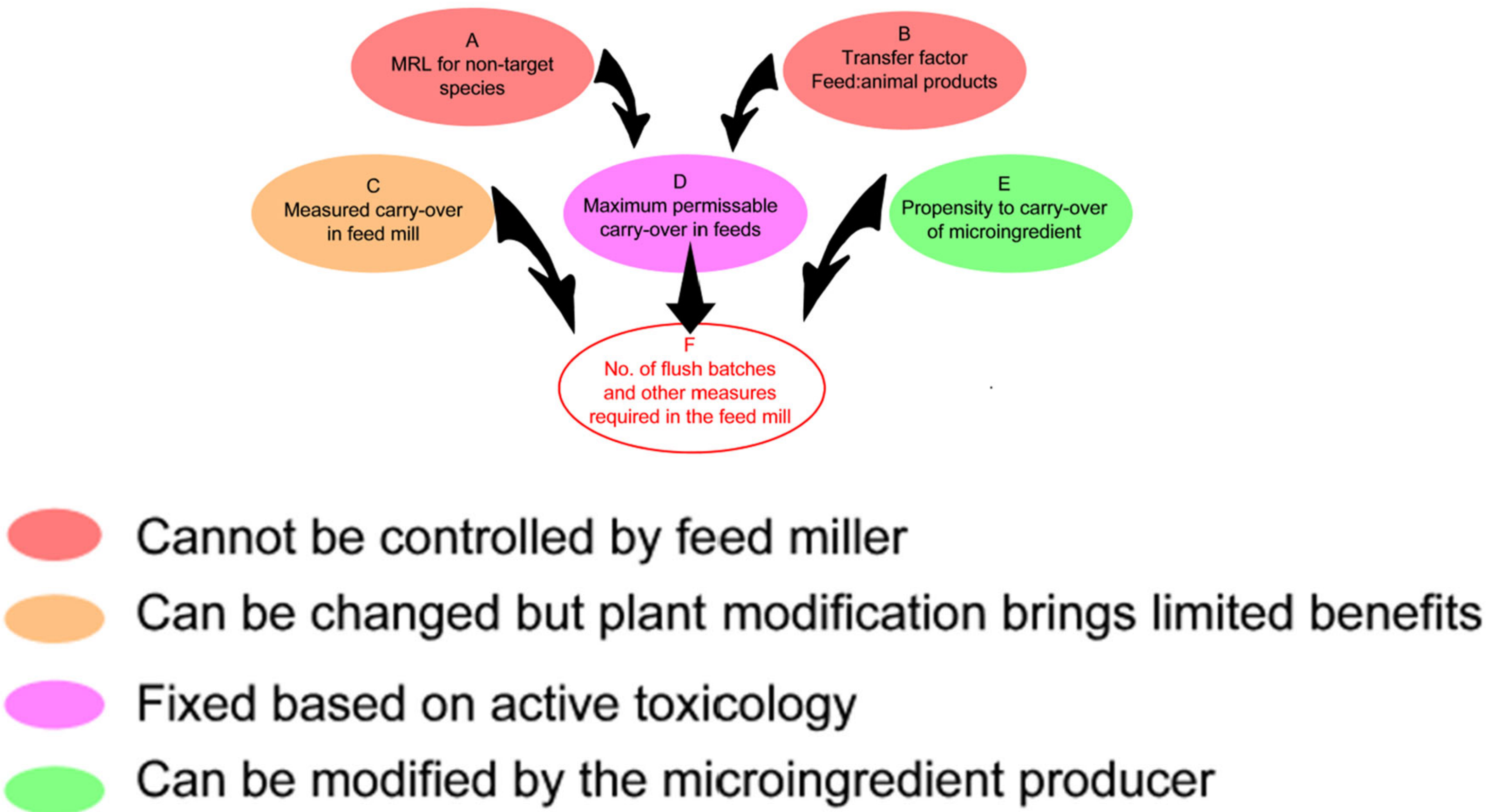
Methods of controlling cross-contamination?

Standard Hierarchy	Reality in Feed Systems
1. Maximum limits in place for safety	❌ Not possible to change ➔ Fixed in law
2. Transfer factor –	⚠️ Limited opportunity ➔ Optimise additive formulations
3. Engineering Controls	⚠️ Partial ➔ Capex required
4. Administrative Controls	⚠️ Variable ➔ Human dependent
5. Personal Protective Equipment	⚠️ Last resort ➔ Does not address root cause

Options for Controlling cross-contamination



Options for Controlling cross-contamination



To conclude

From Theory to Reality

From theory to reality

We've looked at the mechanisms

- Dust
- PD
- Homogeneity
- Particle behaviour

But does this actually happen in the real world?

Yes – and the consequences can be significant

Case Study 1: Selenium exposure in practice

Context

- Tecaliman occupational health study – Loire Valley
- Focus: feed manufacturing environments

Observations

- Evidence of:
  - Dust generation and enrichment
  - Operator exposure to selenium
    - reported symptoms of selenosis including elevated selenium levels in hair samples

Exposure was driven by dust behaviour – not by formulation (high dilution)

Case study 2: horse toxicity / feed mill incident

- Selenium toxicity observed in horses
- Root cause identified as:
  - Dishomogeneity in feed
  - Dust enrichment (PD effect)
  - Elutriation of fine particles
    - Concentrated build up in blow lines – enriched with sodium selenite

Final thought

We don’t lose control because of hazards ....

We lose control because of how materials behave

Control behaviour and you control risk

Thank you

Questions?

If not now – then later?

Feel free to email me

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