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Environmental, Safety & Health Conference 2019

Wednesday 5 June

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Political Strategy or Knee-Jerk Response – What Drives Environmental, Safety and Health Compliance Policy and Procedure?

Matthew Kirk

Regulating Our Future: Key changes for industry and the regulators

Michael Jackson
Head of Regulatory Compliance
Food Standards Agency
13 June 2019

What is the current ROF state of play?

- Our ambition to modernise the regulation of food businesses in England, Wales and Northern Ireland remains as strong as ever
- We have progressed from planning for food regulatory reform to design, delivery and implementation of some key elements of the modernised delivery model
- We continue to work in partnership with a range of stakeholders to develop the new model to make sure that it will be fit for purpose and deliver the desired outcomes

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Register a Food Business

What is it?

- A new digitally enabled approach for registration of food businesses.
- Designed to make it easier for food business operators to register and obtain relevant information and guidance.
- Tested with 11 early adopter LAs and we are scaling up the numbers of LAs using the service.

What's next?

- Maximise LA uptake to enable the benefits of digital registration to be shared with our delivery partners.
- RaFB API release for LAs to collect and import registration data.
- Acting on LA feedback, we recognise there is a need for more flexible approaches to allow LAs to connect to the new service.
- We are exploring how this might work in practice and will be opening up discussions with LAs.

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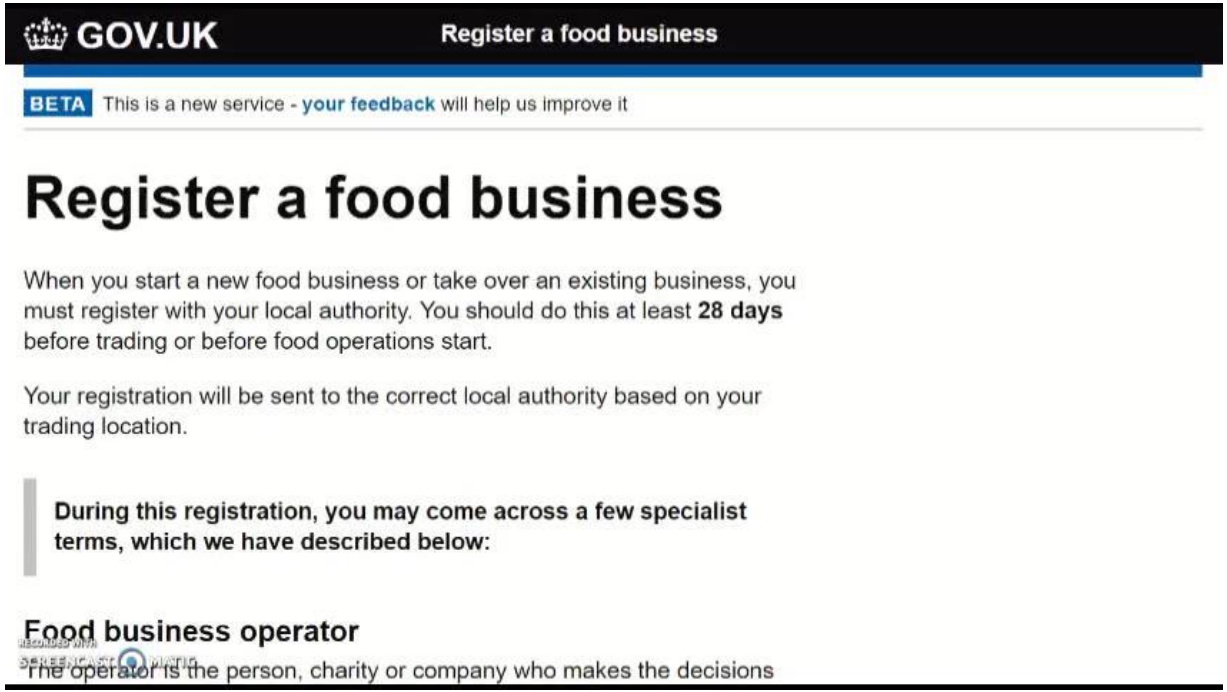
Register a Food Business – Demonstration



RaFB – iterative development

- Acting on early adopter feedback, we have changed how we capture information on partnerships and are working to add additional features such as business opening times and private water supply to the service

- We now require a critical mass of LAs to be using the service to help us with future development

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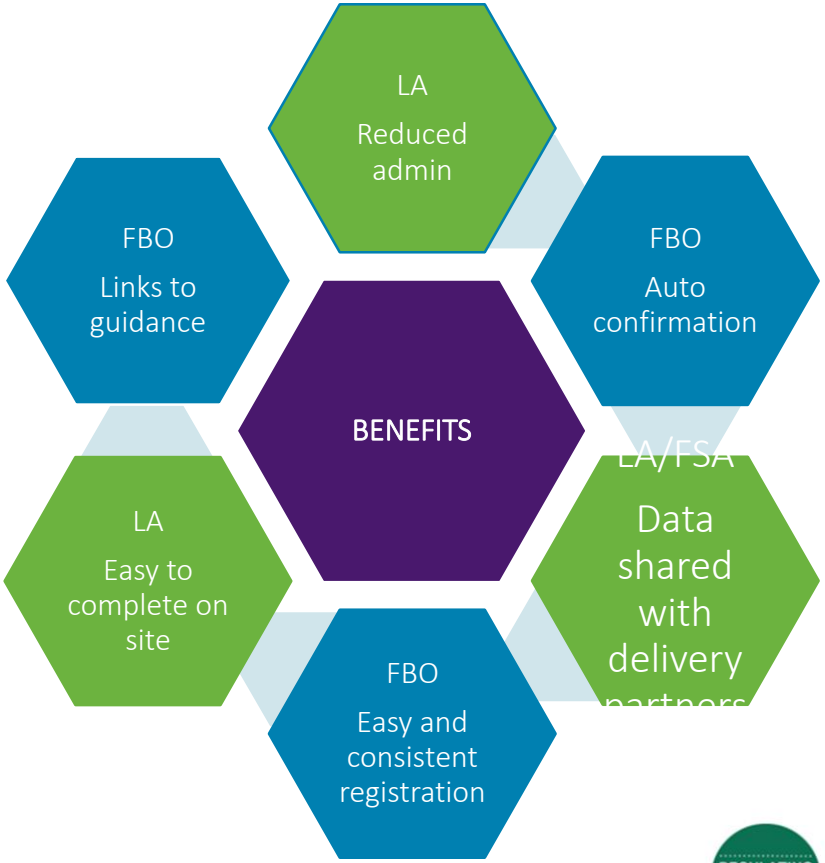
Benefits and Support



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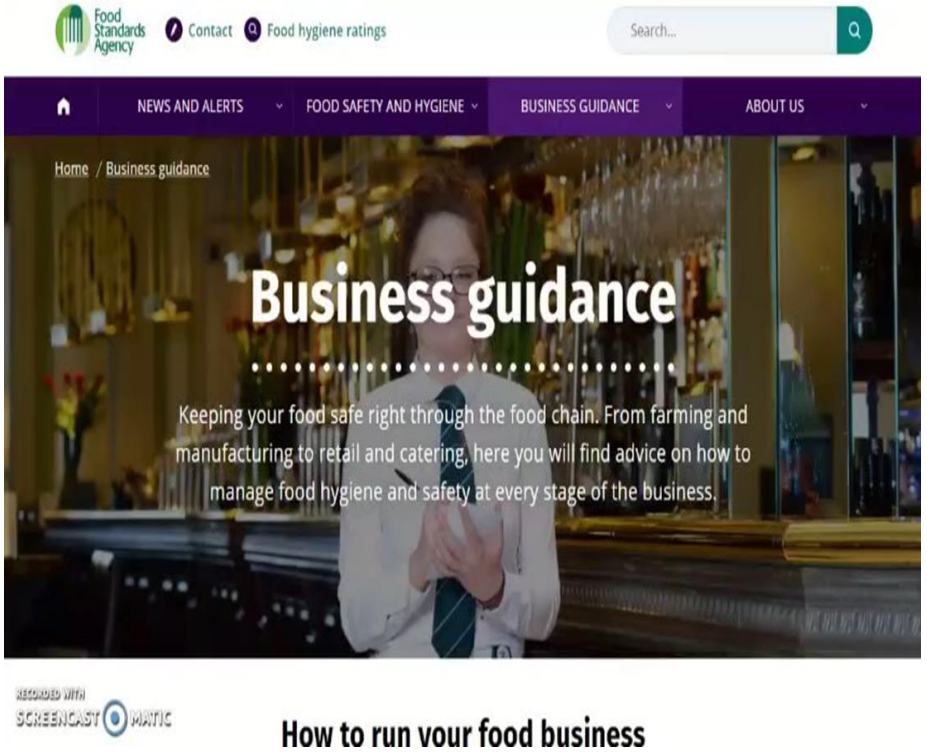
Review of guidance on food.gov.uk

What we are doing

- Reviewing existing content for business guidance.
- Ensuring the content under the business guidance section is informative, easy to find, structured and customer-focused.
- Improving navigation to aid customer journey



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Primary Authority National Inspection Strategies

What it is

- A **primary authority in partnership** with a multi - outlet business, or group of ‘coordinated’ businesses, could decide:
  - That it has sufficient evidence that food safety is being well managed and consider that a more **tailored style or reduced number** of regulatory interventions is warranted.

What we are doing

- We are working with a small number of Primary Authority partnerships that are developing NIS and this is helping test and further shape the FSA’s NIS Standards.
- We anticipate starting live trials in England over the summer months.
- Managing the potential impact of NIS on the FHRS while ensuring the scheme remains robust and credible.
- Inviting enquiries from partnerships interested in working with us to develop NIS for food hygiene and/or standards.

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Food Hygiene Rating Scheme

Requirement

A robust and credible FHRS which continues to operate successfully as part of the changing regulatory system, will enable informed choice and incentivise businesses to improve and maintain standards

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What we are doing

- We are working up options to manage the potential impact that National Inspection Strategies (NIS) could have on the FHRS to ensure we can maintain a robust and credible scheme.
- Publish the results of insight work gathering consumer and business views on managing these potential impacts.
- Working with local authorities to explore options for adapting the FHRS to ensure it continues to operate successfully as part of the modernised regulatory system
- We remain committed to a statutory FHRS in England

Modernising Food Standards Delivery

- We are establishing a new delivery framework that describes an integrated approach to the delivery of Official Controls.
- The integrated approach will include the use of an intelligence model in combination with a new risk rating scheme to inform how Official Controls are planned, prioritised and delivered.
- New approach will be flexible and able to respond to issues as they arise.
- Developing a new competency framework for all food controls – initial focus on increasing the number of people eligible to conduct food standards controls
- Exploring Key Performance Indicators (KPIs) that could apply to the new delivery framework to demonstrate outcomes.

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Food Standards - Next Steps

- Understanding all of the potential impacts change may have on the regulatory landscape and any interdependencies that may exist
- Considering appropriate research projects to inform the above. activity
- Developing a version of the Food Standards training manual for England
- Reviewing the central advice offer available to food businesses

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A framework for the competency of people

What we are doing

- Our aim is to develop a single competency framework for people in the food controls delivery system spanning all relevant roles in the public and private sector
- We will align with international practice and describe the competencies required, rather than in a role or profession – based way.
- We have established a Competency Reference Group to provide a sounding board for proposals and the Chartered Institute of Environmental Health (CIEH) and the Chartered Trading Standards Institute (CTSI) are members of the Group.

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Sustainable Funding

Latest developments

- We remain committed to achieving our ambition to introduce a new funding model to support the modernised regulatory system we are creating, one based on businesses bearing the cost.

Next Steps

- We recognise that it will be some time before we can enact any change and that change will be dependent on cross - Government support for the transfer of regulatory cost to the tax payer.
- We will consider how we can pursue our ambition as part of our work to develop the FSA's strategy from 2020.

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Strategic Surveillance – getting ahead of the curve

To protect the consumer, and ensure that food is safe and authentic, we need to analyse data to understand where issues may arise **before** they become issues

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Working together with Government Departments, academics and industry

Case study : Understanding Olive Oil trade patterns and anomalies

Problem Statement

- Can we use open trade data to identify anomalies in olive oil trade?

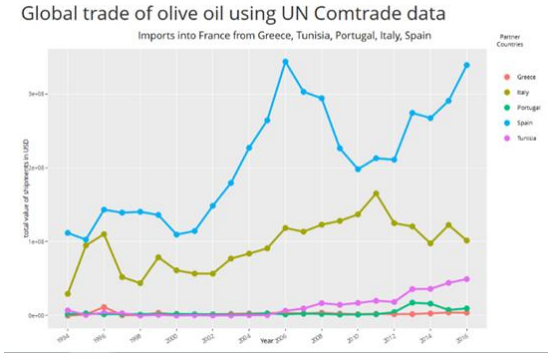
Solution Highlights

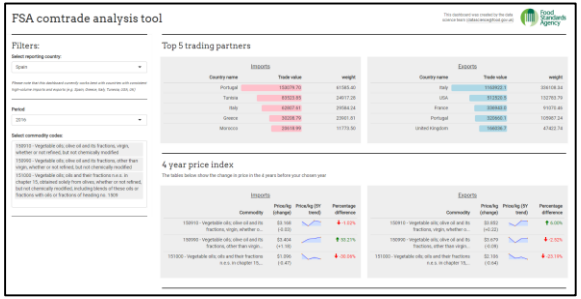
- Used openly available UN trade data to look for patterns in trade of olives and olive oil between countries
- Built a dashboard using this data for further analysis -

  https://foodstandards.shinyapps.io/olivedash_shiny/

Key Findings and way Forward

- Italy is the UKs biggest trade partner for Olive Oil
- In 2017 Italian olive production dropped by 75%, but no drop in Olive Oil trade was observed
- During that time Tunisia exported olives to Italy
- Potentially Tunisian olives are turned into Italian oil and mis-sold





How can you get involved?

We want to continue to listen to the views of those with an interest in food standards and safety and to capture the insights and knowledge that already exists in an open and transparent way.

- Visit our website: https://www.food.gov.uk/about-us/regulating-our-future
- Continue the discussions by joining the conversation #foodregulation or email directly: FutureDelivery@food.gov.uk

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Morning Break

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Accident Investigation

Mea Culpa v Objectivity

Gary Lewis
5 June 2019

Mea Culpa v Objectivity

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Objectivity

- Actual
- Practical
- Uncoloured by one's emotions or sensations

Mea Culpa v Objectivity

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Mea Culpa

- It is my fault
- I am to blame

Mea Culpa v Objectivity

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Investigation of Near Misses or Accidents – Why Bother?

- No express legal duty
- Smart organisations seek to learn from their mistakes
- Important part of an organisation's monitoring and review function ***[Req 5 – Management of Health and Safety at Work Regulations 1999]***
- Generally perceived as a 'force for good'

Mea Culpa v Objectivity

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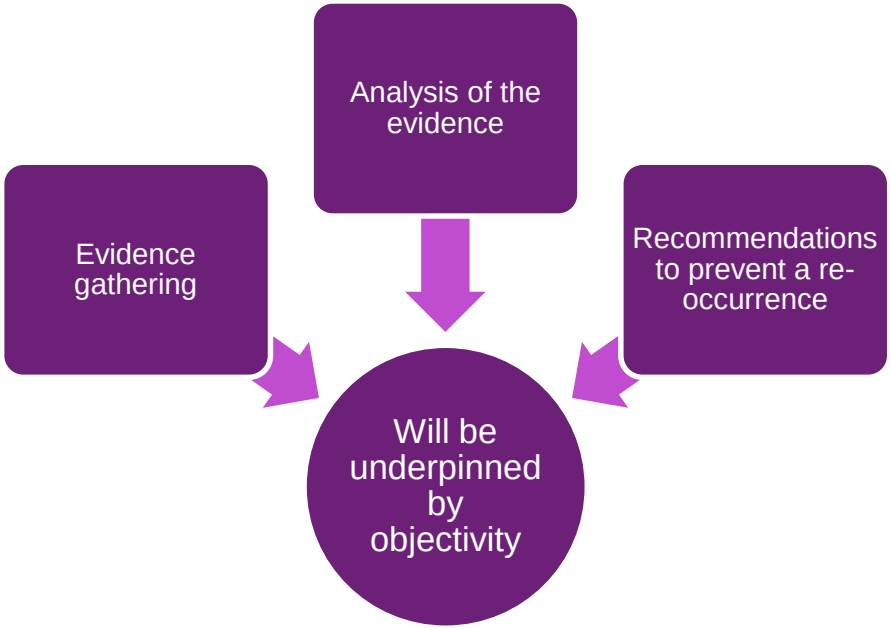
Proposition that investigations are generally a good thing is based upon a number of assumptions



Mea Culpa v Objectivity

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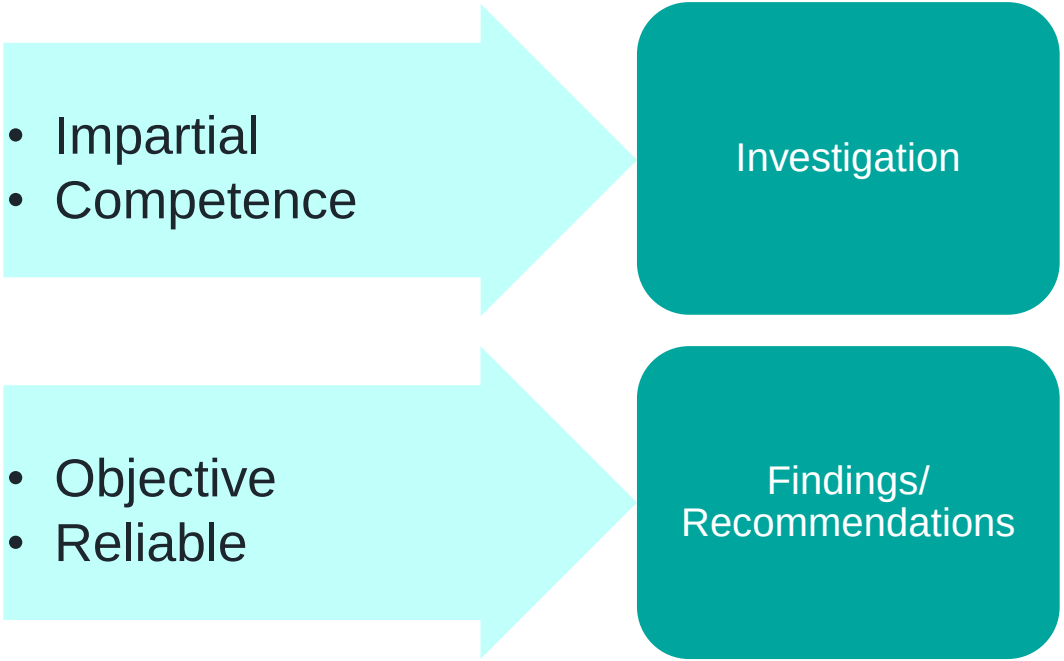
- **Objectives of Investigation and Report**



Mea Culpa v Objectivity

In the immediate/short-term aftermath, following a serious accident, ***perception of risk*** can be ***heightened***

Mea Culpa v Objectivity

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What is the Starting Premise of the Investigation ?

Is it:

- The system of work must be deficient in some way otherwise the serious accident would not have occurred (Mea Culpa)

Or

- Did the system of work incorporate all reasonably practicable steps to either eliminate the risk or reduce it to as low as is reasonably practicable (objectivity) – ***Context is important even if question is intended to be posed neutrally***

Mea Culpa v Objectivity

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If the Starting Premise derives from:-

- Heightened perception of risk
- Mea Culpa perspective
- Real potential for the desired objectivity of the investigation to be lost or seriously undermined
- ***[Add one or more cognitive biases]***

Mea Culpa v Objectivity

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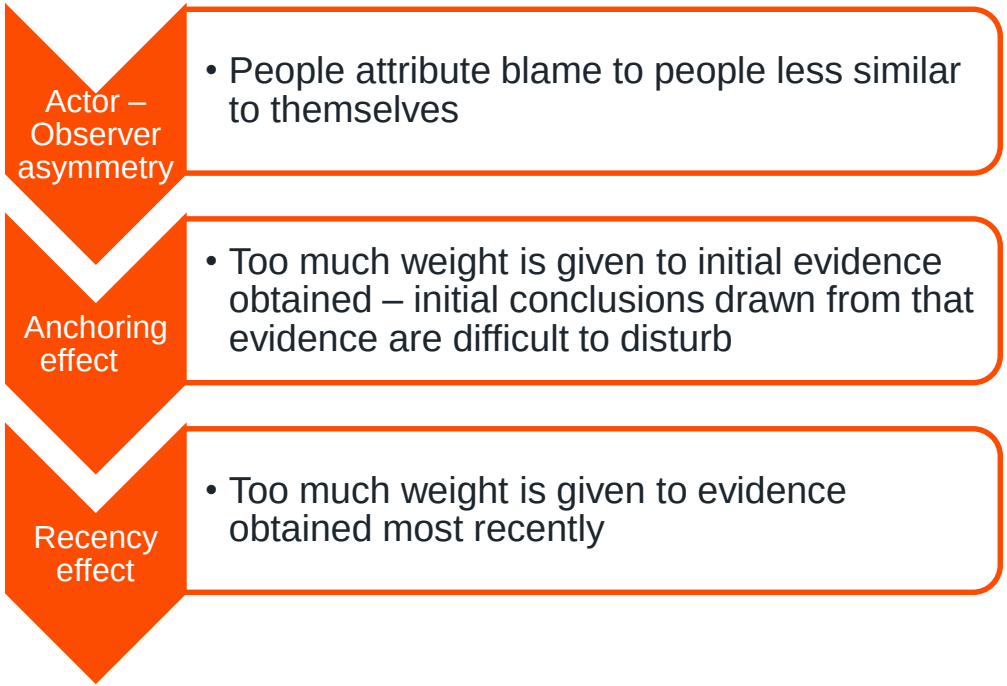
Types of Cognitive Bias

Over 20 types:



Mea Culpa v Objectivity

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Types of Cognitive Bias

Over 20 types:

Confirmation bias

- Once we have a theory it can be difficult to adjust our position. Natural tendency to look for more information that confirms initial theory and discount information that does not

Mea Culpa v Objectivity

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Types of Cognitive Bias

Over 20 types:

Handsight bias

- The perception that the probability of a risk manifesting is higher that it actually was, because the risk has, in fact manifested

Outcome bias

- Judging a decision by its eventual outcome as opposed to looking at the circumstances or information available at the time the decision was made

Mea Culpa v Objectivity

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A Bit of Law

Sections 2 & 3 of the Health & Safety at Work Etc. Act 1974.

- General duties imposed on Employers in respect of employees and non-employees.
- Reverse burden of proof if HSE can establish real risk arising from activity.
- Qualified by reasonable practicability – cost benefit analysis approach – Risk v Sacrifice (time and money).

Mea Culpa v Objectivity

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A Bit of Law

HTM Ltd – Court of Appeal, May 2006.

- Foreseeability is a ***component*** of the reasonably practicable test.

Mea Culpa v Objectivity

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A Bit of Law

- It is settled law that the test of reasonable foreseeability should be applied prior to and not after the incident or accident that is the subject of the prosecution.

- To ensure that the test of reasonable foreseeability is not distorted by the benefit of hindsight in applying post-accident knowledge to pre-accident circumstances.

- The legal test of Reasonable Practicability incorporating Reasonable Foreseeability suggests that Hindsight and Outcome biases are recognised as having the potential to distort the reasonable practicable test and the resultant defence and should be guarded against.

Mea Culpa v Objectivity

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What is the Effect of this in Practice?

Control measures that would not objectively be viewed as reasonably practicable pre-accident are viewed as reasonably practicable and implemented post-accident.

Why?

Because the system of work was pre-judged as being deficient from the outset of the investigation because of a combination of:-

- Mea Culpa mentality
- Heightened perception of risk
- Hindsight bias
- Outcome bias

Mea Culpa v Objectivity

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Beware Accident Investigation Models:-

- 5Whys – heavily geared towards establishing cause/steps to prevent a reoccurrence
- HSG 245 – heavily geared towards establishing “management failure” as root cause

Mea Culpa v Objectivity

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The Prosecution Approach

- Compare and contrast pre-accident and post-accident systems of work
- Control measures implemented post-accident are identified as the ‘safety deficit’
- Once a control measure is implemented post-accident it will be difficult to argue that it was not reasonably practicable to implement it pre-accident
- In practical terms the only defence has gone

Mea Culpa v Objectivity

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What to do to Inject some Objectivity into the Exercise:-

- Appoint someone within the accident investigation team to be a ‘sense checker’

- Appoint someone outside the accident investigation team to challenge the evidence, analysis of the evidence and/or recommendations:
  - In house Counsel
  - External lawyer (who may be instructed to assert LPP over report)
  - External accident Investigator
  - External H & S Consultant

Mea Culpa v Objectivity

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If Technical Issue:-

May need expert to comment on reasonably practicable steps [should be appointed by lawyer to comment in form of a report covered by LPP]

Mea Culpa v Objectivity

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The Accident Investigation Report is covered by LPP so we are ok?

- Operational changes to risk assessments, safe operating procedures and/or physical changes to work equipment are not covered by LPP
- Prosecution can still do compare and contrast exercise absent the accident investigation report

Mea Culpa v Objectivity

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Conclusion

Any changes to a system of work post-accident should be objectively scrutinized before they are adopted in the Report and/or implemented in practice

Note – Change to RIDDOR Report Form

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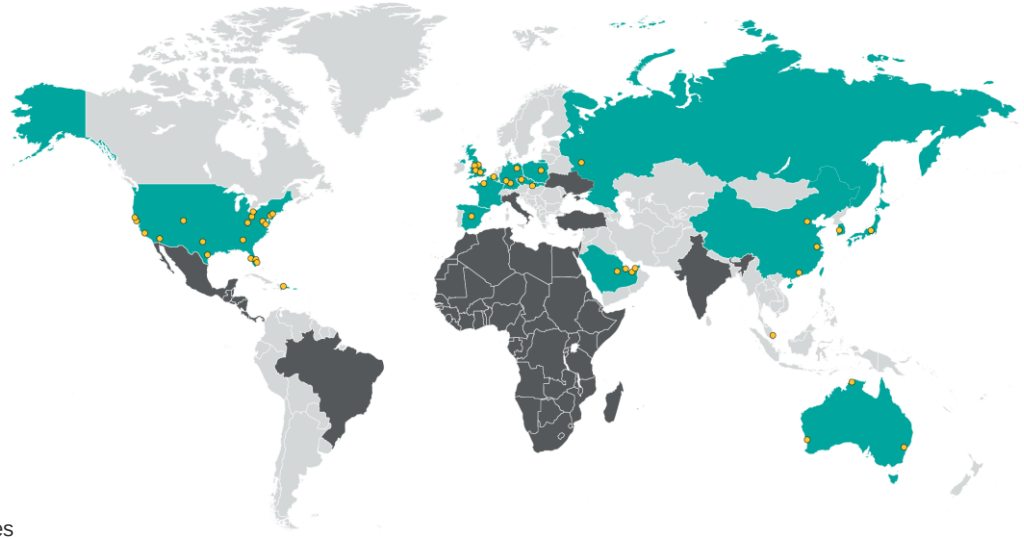
Global Coverage

Abu Dhabi
Atlanta
Beijing
Berlin
Birmingham
Böblingen
Bratislava
Brussels
Cincinnati
Cleveland
Columbus
Dallas
Darwin
Denver
Doha
Dubai
Frankfurt
Hong Kong
Houston
Leeds
London
Los Angeles
Madrid
Manchester
Miami
Moscow
New Jersey
New York
Northern Virginia
Palo Alto
Paris
Perth
Phoenix
Prague
Riyadh
San Francisco
Santo Domingo
Seoul
Shanghai
Singapore
Sydney
Tampa
Tokyo
Warsaw
Washington DC
West Palm Beach

Africa
Brazil
Caribbean/Central America
India
Israel
Italy
Mexico
Turkey
Ukraine



Office locations

Regional desks and strategic alliances

SIEMENS
Ingenuity for life

After the Event

Managing the return to continual improvement following a major incident

Louise Ward
HSEQ Director Siemens Mobility

Louise Ward

HSEQ Director Siemens Mobility

Louise Ward is a Chartered Health and Safety Practitioner with over 20 years experience. Her career has spanned a range of business sectors and high profile companies including British Nuclear Fuels, News International. BP, JP MorganChase, the Engineering Employers Federation, the Civil Service, Network Rail, Thames Water, and the British Safety Council. She is now Health, Safety, Environment and Quality Director for Siemens Mobility, overseeing rail and traffic management operations across the UK.

As well as being a practicing health and safety specialist, Louise has been involved in the development of legislation, guidance material and regulatory policy. She has a particular interest in professional development and supports a number of initiatives in this area. She is a visiting lecturer at Middlesex University and a member of a trailblazer group developing degree level apprenticeships. Louise writes regularly for the trade press, and recently co-authored a handbook about wellbeing which has been published by Routledge.

Maslow's Hierarchy of Needs

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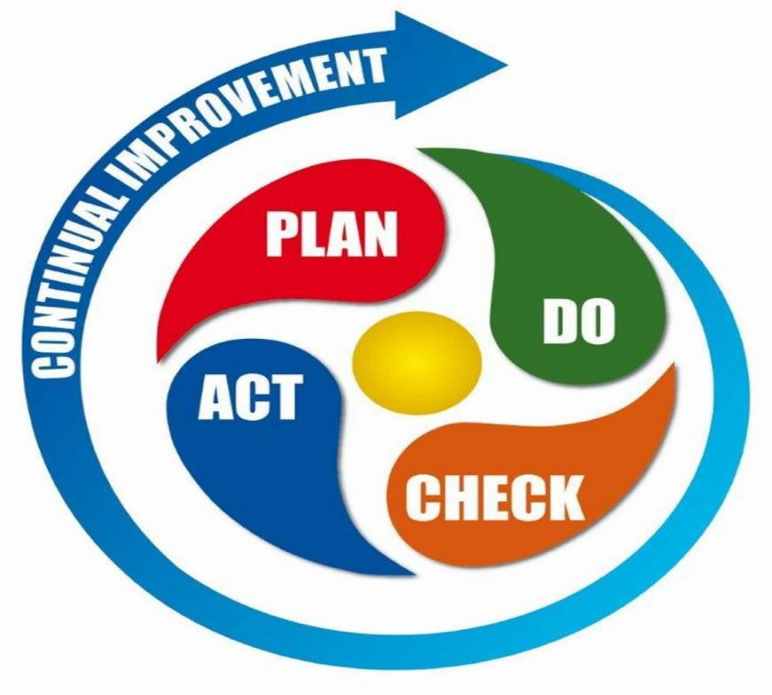
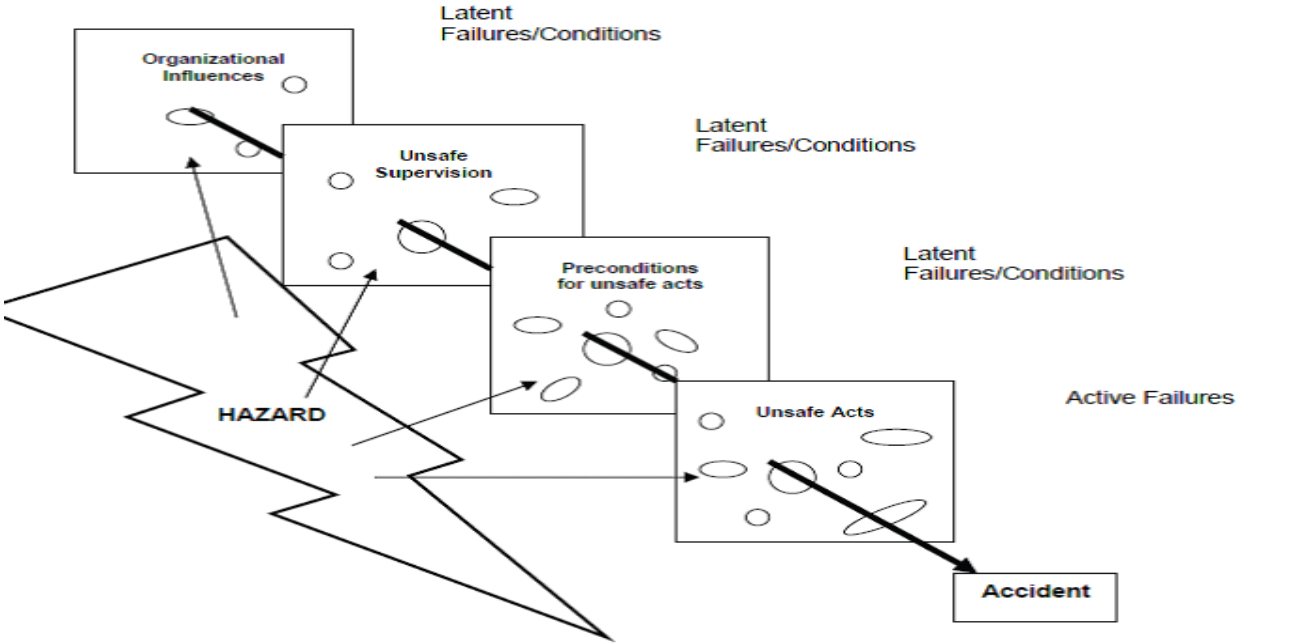
Stress Response

Purpose of a Safety Management System



everyone
home safe
every day

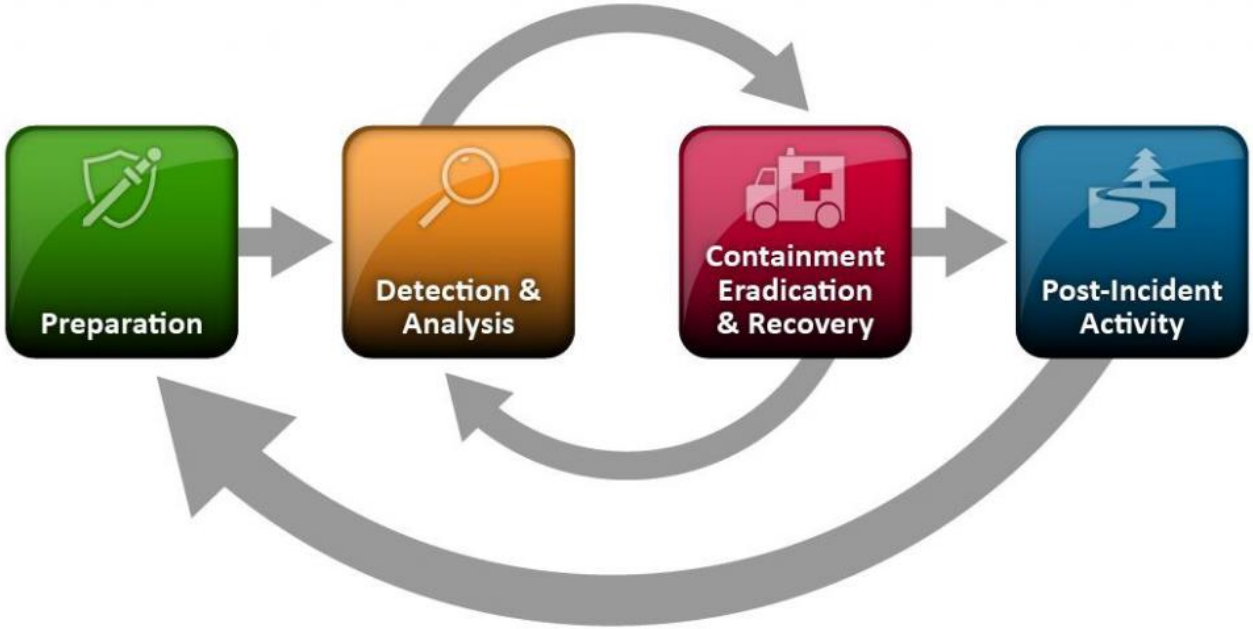
Possibility of Failure



Adopted from "Managing the Risks of Organizational Accidents by J. Reason, Cambridge, U.K.: Ashgate

Impact

Incident Lifecycle



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Ingenuity for life

7 Stages of Grief

(Modified Kubler-Ross Model)

Shock*	• Initial paralysis at hearing the bad news.
Denial	• Trying to avoid the inevitable.
Anger	• Frustrated outpouring of bottled-up emotion.
Bargaining	• Seeking in vain for a way out.
Depression	• Final realization of the inevitable.
Testing*	• Seeking realistic solutions.
Acceptance	• Finally finding the way forward.

*This model is extended slightly from the original Kubler-Ross model, which does not explicitly include the Shock and Testing stages. These stages however are often useful to understand and to facilitate change.

Managing Recovery

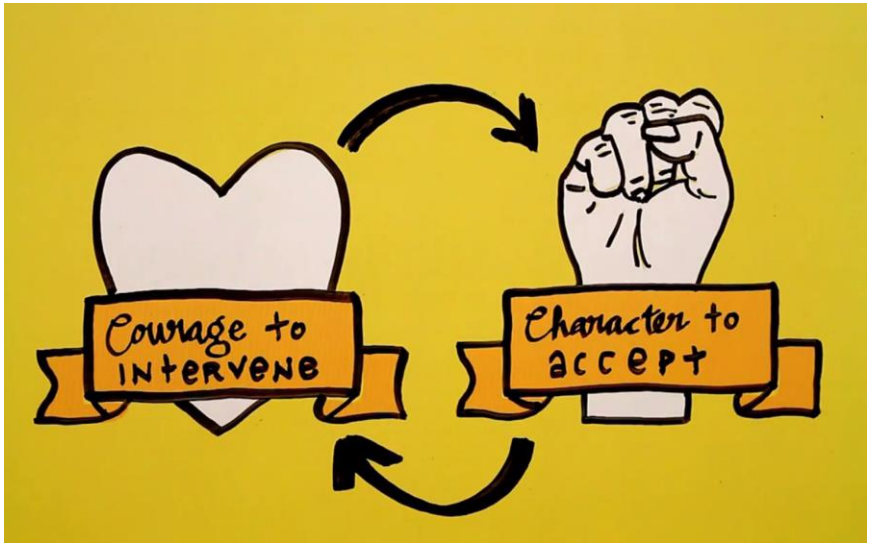
- Acknowledge failure
- Respect impact
- Target areas for improvement
- Call to arms
- Focused improvement programme
- Manage risks of engagement
- Realistic pace of change

Essential Elements

- Leadership
- Core Team
- Positivity and drive
- Report progress regularly
- Manage expectations
- Apply lessons learned
- Celebrate successes

- *Personal Resilience*

Small Things Make a Difference



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Environmental, Safety & Health Conference 2019

Lunch Break

Leeds City Council

Polly Cook
Leeds City Council
5th June 2019

Clean Air Leeds

Legal Timeline

- 2010 Air Quality Standards Regulation enshrined all EU Air Quality Laws into UK Law.

- In 2015, Leeds named by DEFRA as one of 6 cities which will not be compliant with EU & UK limits of 40µg/m^3 for nitrogen dioxide levels by 2020.

- Client Earth launched successful legal action on the government in April 2015 and November 2016 based on these plans being insufficient.

- July 2017, Government released Revised National Air Quality Plan naming Leeds as one of 28 cities required to implement a Clean Air Zone.

- February 2018, third Client Earth court case concluded. Now includes Bradford, Wakefield, Calderdale and Kirklees

Why are we taking action to improve air quality?

Health benefits
Approximately 40,000 premature deaths per year are attributable to poor Air Quality in the UK.

Compare this to…
Passive Smoking: 10,700 deaths
(source BMJ 2005, published online 1 March 2005)

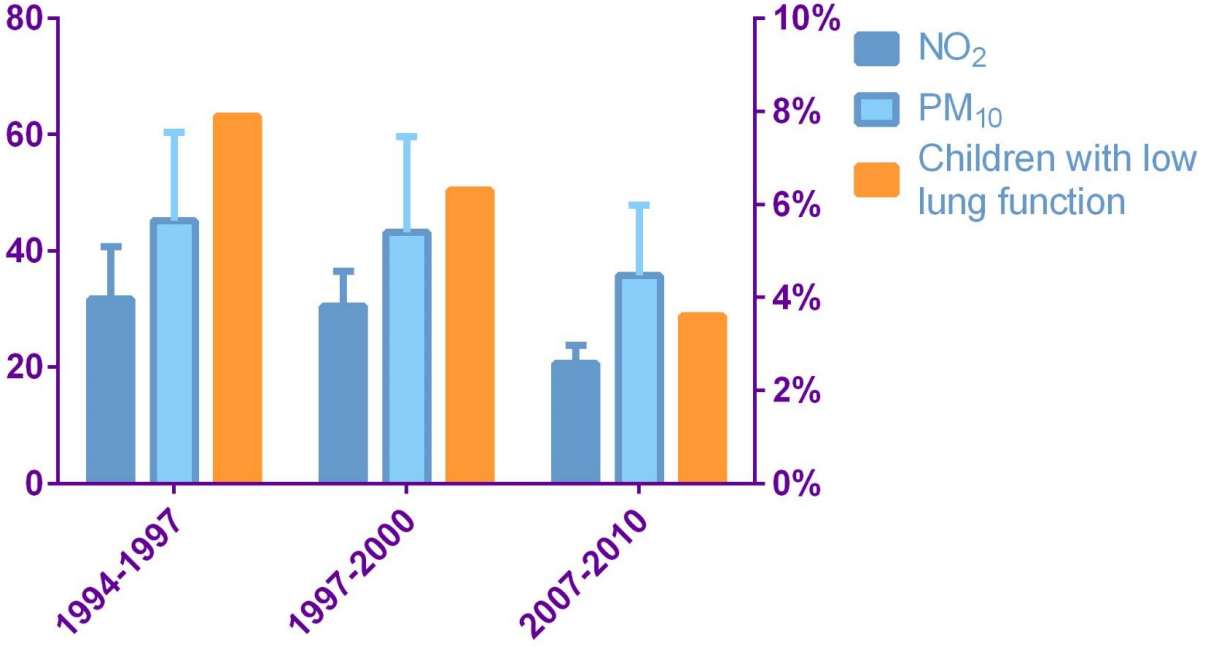
Susceptible groups

- Children
  - Increased respiratory volume per weight
  - More sensitive to airways irritation and higher risk of developing infections
- Elderly
  - Poorer immune systems and less reserve
- Pre-existing conditions
  - Asthma / COPD
- Pregnancy
  - Reduced birth weight and increased maternal complications

Southern California experience

- Historically plagued by high pollution levels
- Number of interventions to reduce air pollution
- Air pollution trending downwards

Improvements in pollution and lung function



Public perception and understanding

- When surveyed in early 2018 as part of the first CAZ consultation, 77% of residents agreed that tackling air pollution was an urgent priority for the city.
- Awareness has grown since then: local and national media coverage of air quality related stories has increased significantly over the past two years.
- However, it is unclear whether growing awareness = better understanding.
- In 2018, we commissioned focus group research to explore public understanding of air pollution in Leeds. This found that…

Public perception and understanding

Residents are…

- Aware that air pollution is an issue, but do not understand its damaging health effects or are sceptical of them—especially cancer links.
- Confused about the distinction between air pollution and climate change, which they feel powerless to influence.
- Generally unaware (or don't believe) that their car journeys contribute to air pollution in Leeds.
- Wary of public transport as an alternative to driving: it is seen as expensive, unreliable, and inconvenient.
- Wary of cycling as an alternative to driving: it is seen as unsafe.
- Willing to reduce the number of walkable, short journeys that they currently take by car.
- Believe that the local authority is most responsible for improving local air quality—but that everyone shares some responsibility.

Exposure levels – Pedestrians vs Vehicles

There is a common misconception that the air outside a car on a busy road is more polluted than inside

Higher air pollution health risk inside car, study finds

Air pollution more harmful to children in cars than outside, warns top scientist

Pollution is worse in your car than on street

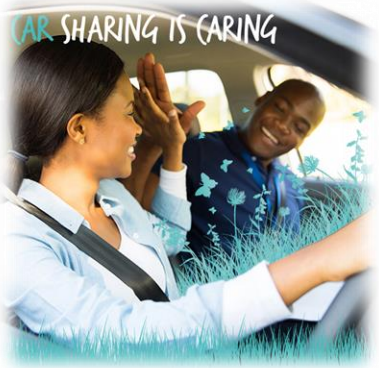
"It's nine to twelve times higher inside the car than outside. The car is…sucking the fresh exhaust coming out of the car or lorry in front of them straight into the back of the car." Prof Stephen Holtate, Southampton University

"Levels are significantly lower at the side of a road than in traffic." Dr Ben Barratt, KCL

What is already happening?

Transport Investment

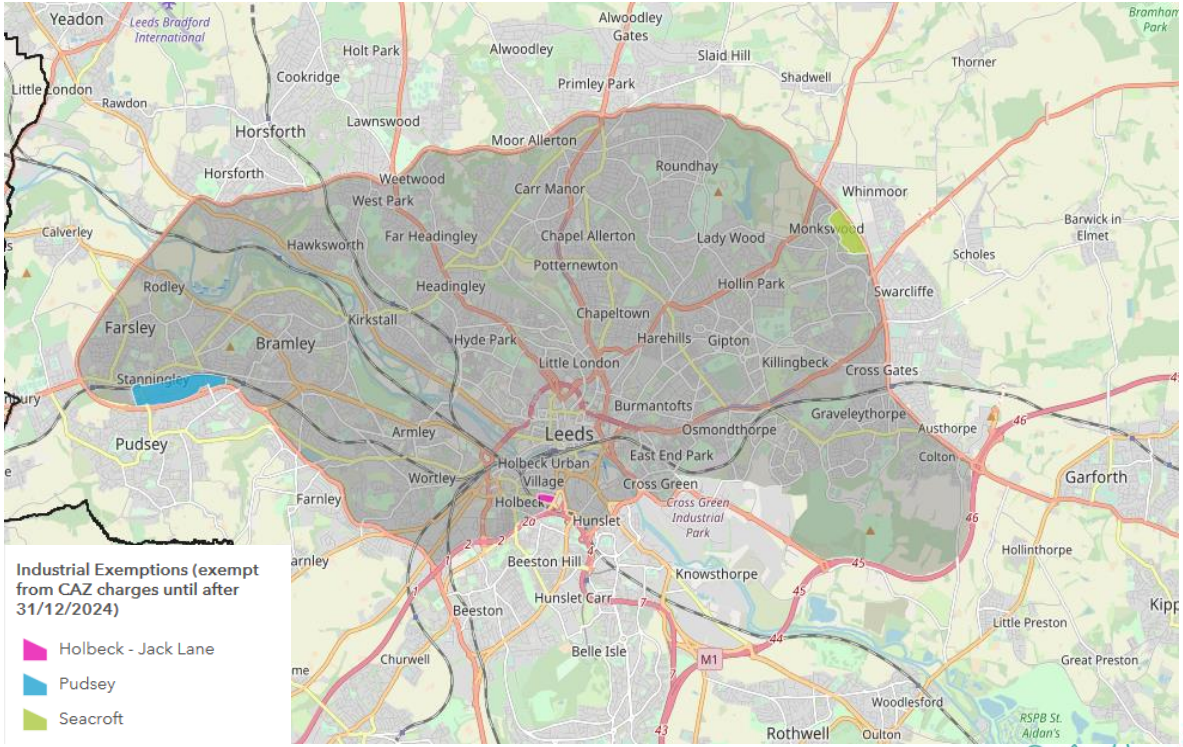
Early Measures Funding (£2.8 m)



Breathe clean by going green

Alternative Fuel Vehicle Fleet

Leeds CAZ boundary map **(89 sq. kms.)**

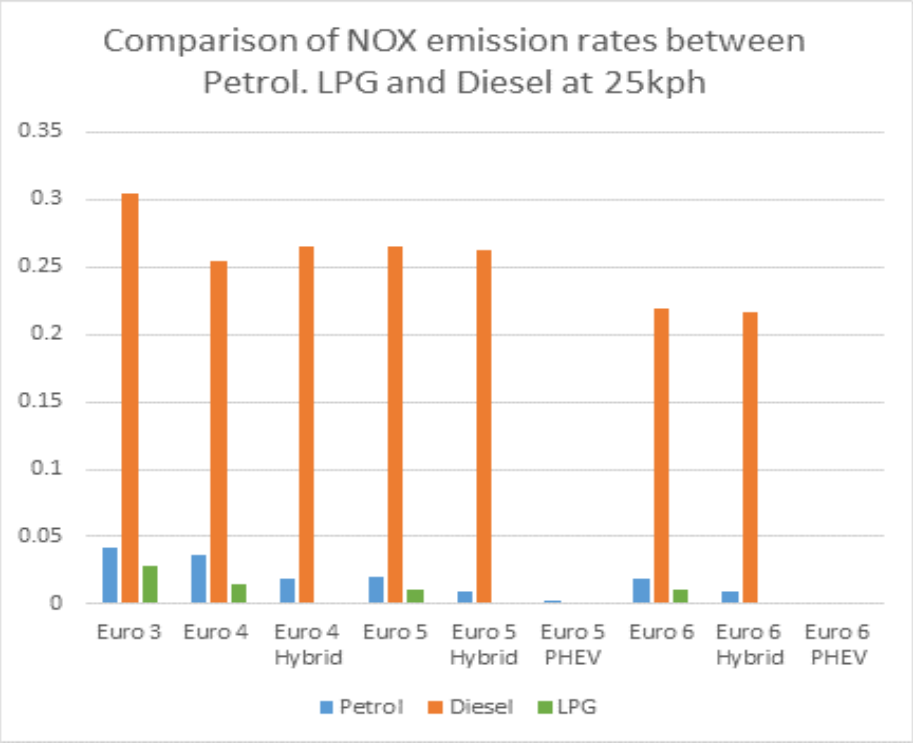


The Leeds Clean Air Zone

Clean air zone class	Vehicles Included
A	Buses, coaches and taxis & private hire (T&PH) M3 (GVW over 5000 kg and more than 8 seats in addition to the driver) M2 (GVN not exceeding 5000 kg, ref mass exceeding 2610 kg and more than 8 seats in addition to the driver)
B	Class A + Heavy Goods Vehicles (HGVs) N2 (GVW over 3500 kg and ref. mass over 2610 kg) N3 (GVW over 5000 kg)
C	Class B + Light Goods Vehicles (LGVs)
D	Class C + private cars

Taxi and private Hire will be charged **£12.50** per day to enter the zone in a non-compliant vehicle (or **£50pw** for Leeds licensed drivers)
Buses, Coaches and Heavy Goods Vehicles will be charged **£50** per day to enter the CAZ in a non-compliant vehicle.

Euro 6 performance in smaller vehicles



Smaller vehicles such as cars and vans are not providing the emissions savings of larger vehicles, especially in real life test situations at EURO 6

Practicalities

- Signage will be developed nationally
- National Payment Portal (implemented by government)
- Any non payment of charge will be enforced locally
- Two rings of ANPR cameras around the city (funded by government grant)
- Payment will be due by midnight of the day after you enter the zone

What happens to the revenue raised?

- Ring fenced funding

- Can only be spent to cover scheme running costs, and air quality improvement initiatives

- Could include further grants to help businesses upgrade vehicles or facilitate further ULEV uptake

The Clean Van Commitment

- A public pledge to move to zero emission vans in cities by 2028
- Vans contribute 30% of UK road transport's NO2 emissions and are the fastest growing vehicle type in the country
- The annual health cost to the NHS and wider society from older diesel vans is estimated at £2.2 billion
- 16 initial signatories

Van Scheme

- Business engagement to support the uptake of ULEV vans in the city through:
    - Technical advice
    - Vehicle trials

Climate Emergency

Safe work with manufactured nanomaterials

Delphine Bard, Health and Safety Executive, Science Division, Buxton UK

delphine.bard@hse.gov.uk

Introduction

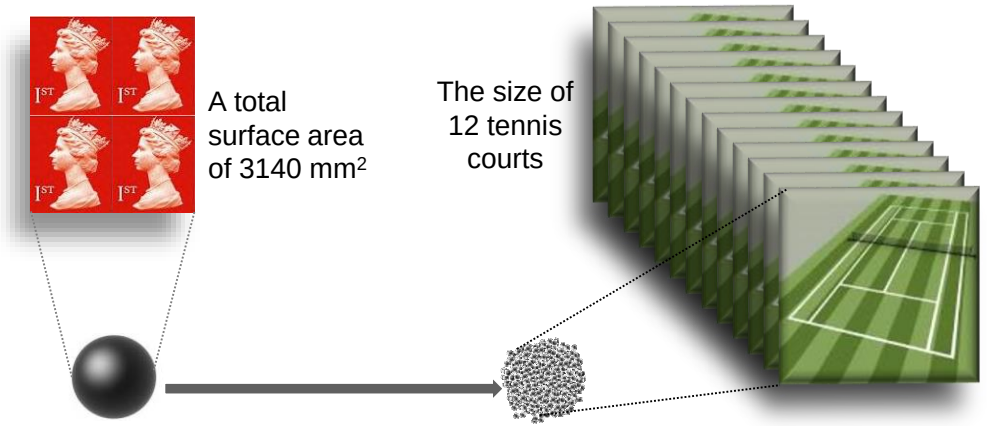
- Safe development of new technology can bring high benefits to people's life and businesses
- HSE committed to work together with a wide range of stakeholders to tackle the problems of tomorrow today

- New materials include:
  - **Nanomaterials and nanoparticles**
  - **New fibres**
  - **Advanced composites**
  - **Metal powders**

Source: National Nanotechnology Infrastructure Network

Approach: Understanding risks and control measures across the lifecycle of the material

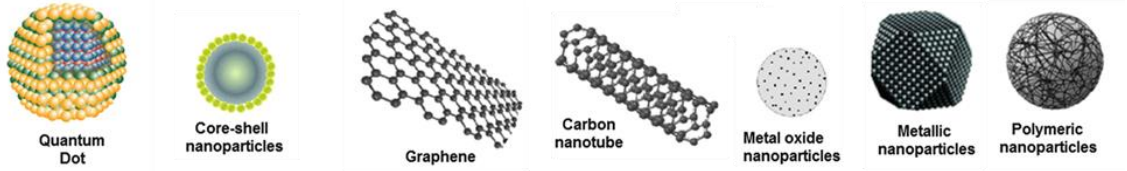
Are nanoparticles a risk to health?



- Enhanced exposure due to small size
- Surface area very large compared to their mass
- Toxicity proportional to surface area not mass
- Novel surface properties
- Persistence and bio-accumulation

What are the potential challenges?

- “Nanoparticles” are a wide class of particulate substance



No single measure of toxic potency can be attributed to all nanoparticles as not all nanoparticles are toxic nor equally hazardous

- The definition of the size cut-off for NP has no basis in toxicology

No step-change in toxicity when a particle becomes below 100 nm in any dimension.

Figure adapted from Cerro-Lopez M., Méndez-Rojas M.A. (2017). In: Gómez-Oliván L. (eds) Ecopharmacovigilance. The Handbook of Environmental Chemistry, vol 66. Springer, Cham

What are the potential challenges?

- Case by case approach for the risk assessment

(Regulatory) toxicology challenging, expensive, and slow

Computer models and grouping / read across being developed

'Precautionary' approach

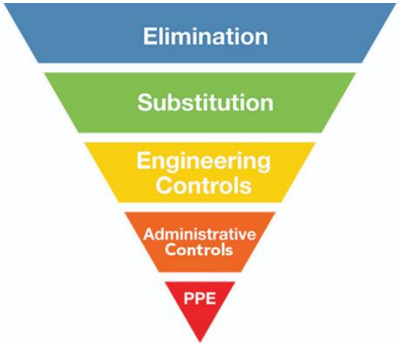
- Different properties compared to the "parent material"

- Mixtures of materials and contamination

- Workers currently handling nanomaterials : the safety data (SDS) can be incomplete and limited

Risk assessment and risk management

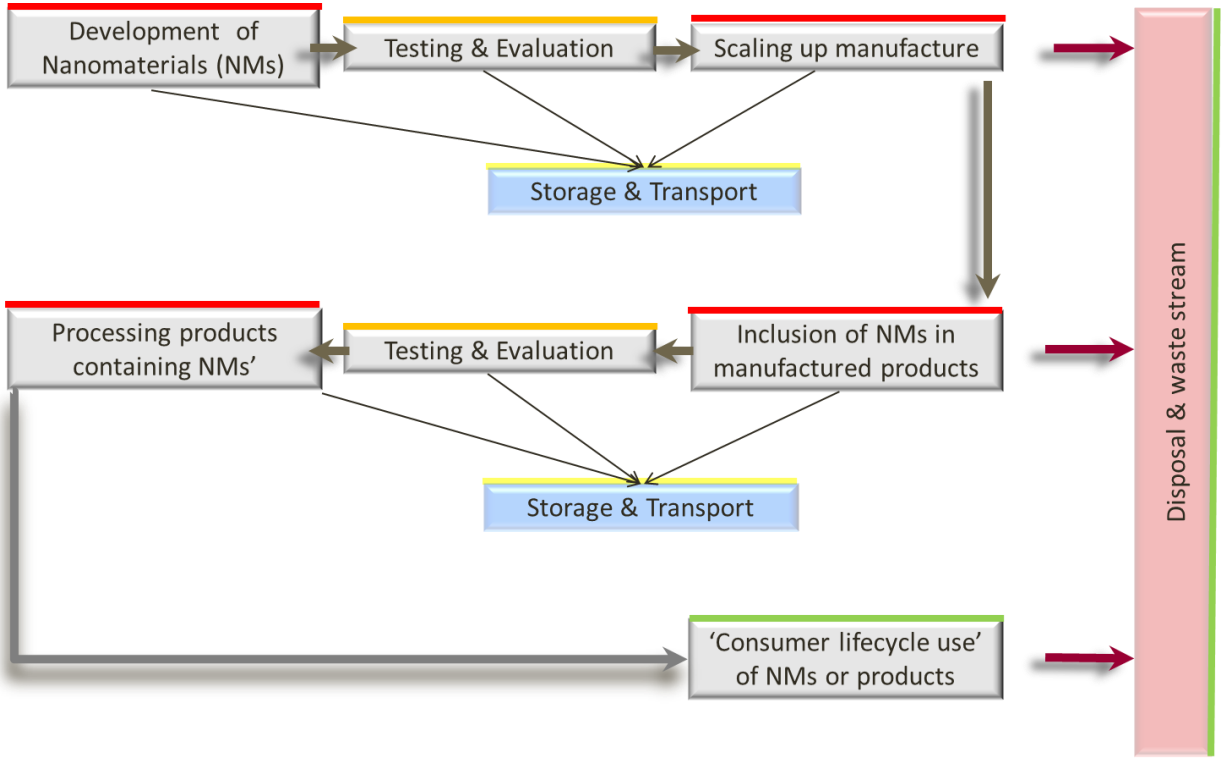
- Risk = Hazard x Exposure
- Control Banding: generic technique that determines a control measure based on a range or “band” of hazards and exposures
- Safety by design
- Hierarchy of controls:



Workplace

Waste

Lifecycle of nanomaterials



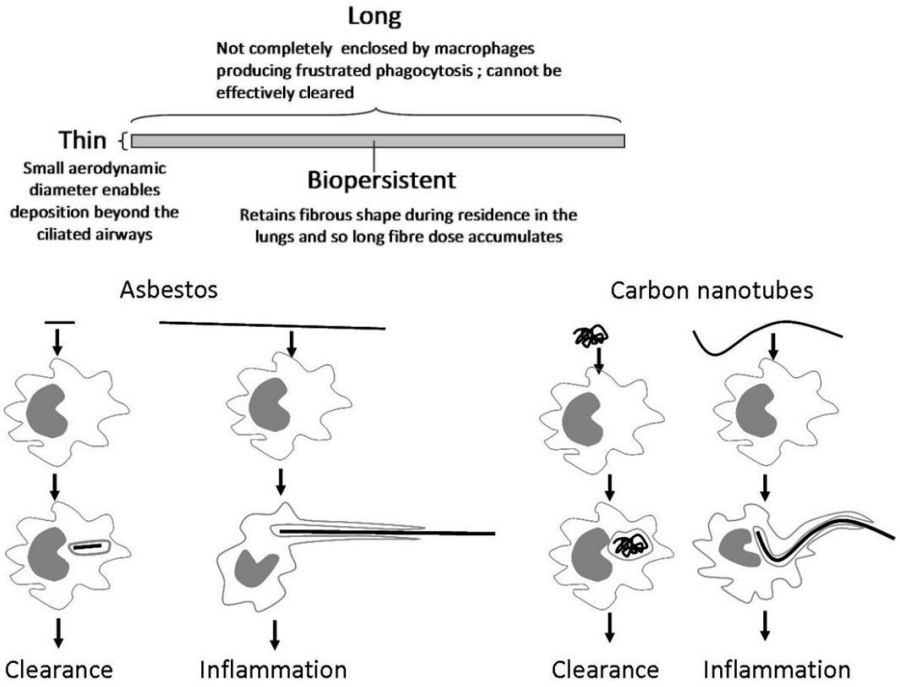
Hazard

Attributes that influence toxicity of nanomaterials:

- Is the particulate classified as a CMTR (carcinogen, mutagen, teratogen and reproductive toxicant) or sensitizer?
- Is the nanomaterial composed of reactive metal(s)? Is the nanomaterial photoreactive?
- Does the nanomaterial have a highly charged surface?
- Is the (nano)material soluble?
- Is the nanomaterial fibrous (i.e. possess a high aspect ratio)?
- Does the nanomaterial possess a low aerodynamic diameter yet one or more high aspects?

- Not all nanoparticles are toxic nor equally hazardous

Hazard - HARN



Source: Donaldson et al. Particle and Fibre Toxicology 2010, 7:5

- Long-Fiber Carbon Nanotubes Replicate Asbestos-Induced Mesothelioma with Disruption of the Tumor Suppressor Gene Cdkn2a (Ink4a/Arf). Chernova T and al. 27, 3302-3314 (2017)

IARC Monograph 111 - CNTs

- Cancer in humans
  - I*nadequate evidence* in humans for carcinogenicity of CNTs
- Cancer in experimental animals
  - S*ufficient evidence* in experimental animals for carcinogenicity of MWCNT-7
  - *Limited evidence* in experimental animals for carcinogenicity of two types of MWCNTs with dimensions similar to MWCNT-7
  - *Inadequate evidence* in experimental animals for carcinogenicity of MWCNTs other than MWCNT-7
  - *Inadequate evidence* in experimental animals for the carcinogenicity of SWCNTs

Overall evaluation

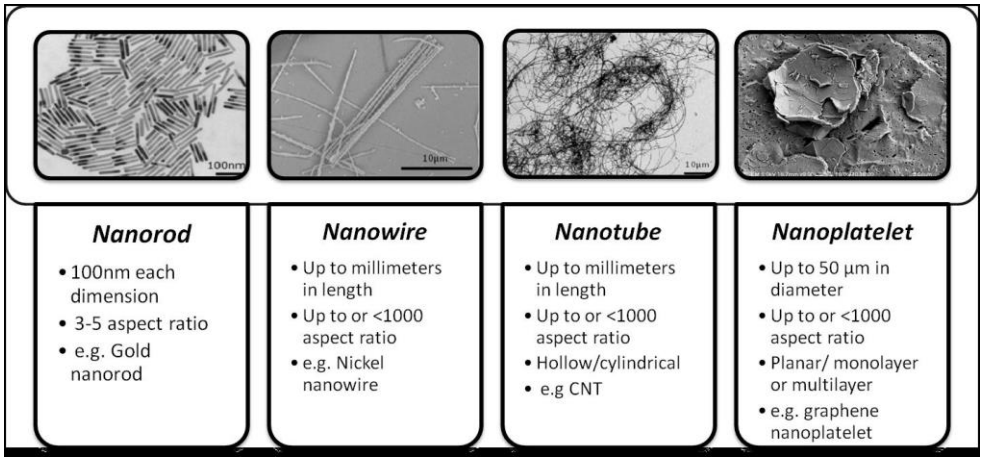
MWCNT-7 *possibly carcinogenic to humans* (Group 2B)

MWCNTs other than MWCNT-7 *not classifiable* as to their carcinogenicity to humans (Group 3)

SWCNTs *not classifiable* as to their carcinogenicity to humans (Group 3)

Current debate

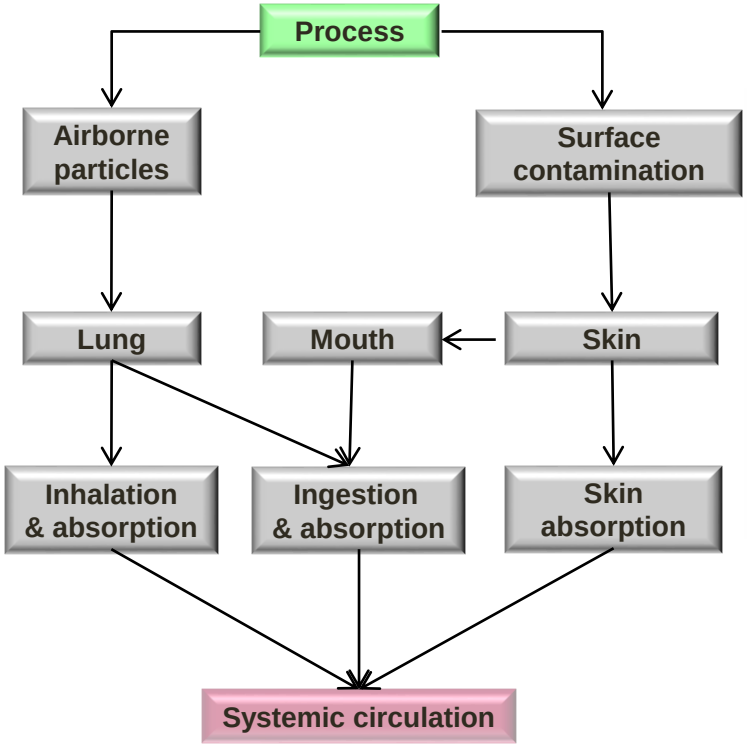
- Are graphene HARN?

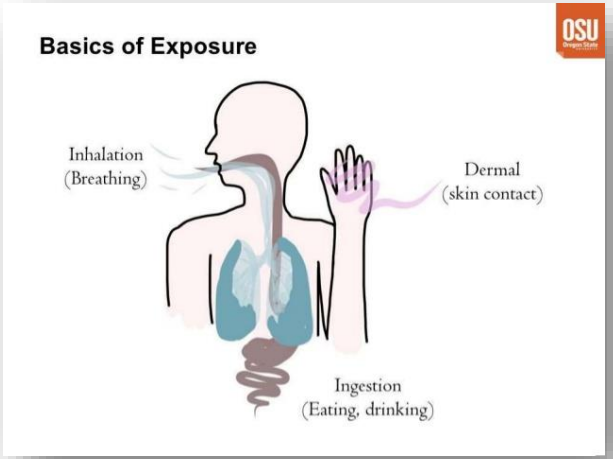


Very thin plate-like particles, which are large but with small aerodynamic diameters and may not be dealt effectively by normal lung clearance mechanisms

Source: Anja Schinwald. The toxicology of high aspect ratio nanomaterials - How shape determines the biologically effective Dose. Presented for the degree of Doctor of Philosophy. The University of Edinburgh. 2013

Exposure route and pathways





Souce: Orlando state University

Practical exposure measurement

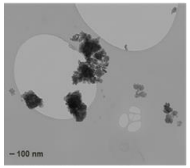
Information gathering

Conventional sampling - Mass

Real-time background and task - Number or surface area

Physico-chemical characterisation

- Electron microscopy
- XRF / ICMPS
- Thermo-optical carbon analysis



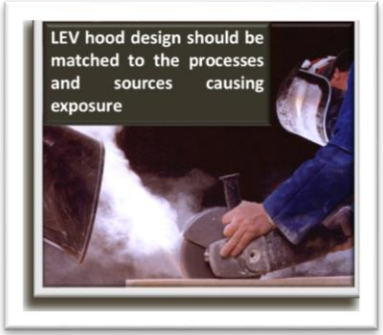
Contextual information

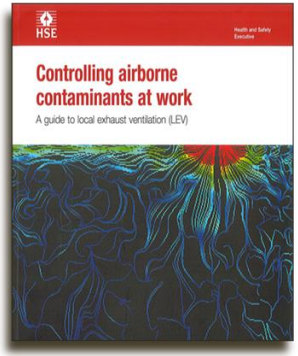
Photo courtesy of Mark M Methner, Ph.D. CIH (NIOSH)

Local Exhaust Ventilation and engineering control

- Methods for routine exposure measurements shall integrate engineering control assessment. Shall be pragmatic and practical:
  - Practical measurement strategies for the process and the type of nanoparticles being assessed
  - Contextual information - Important
  - Occupational hygiene assessment of the effectiveness of the control measures – Important

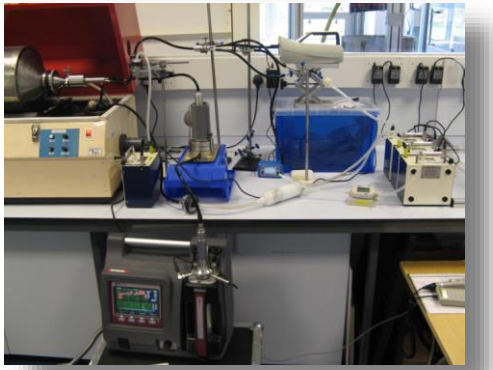
- HSG 258 “Controlling airborne contaminants at work: A guide to local exhaust ventilation”





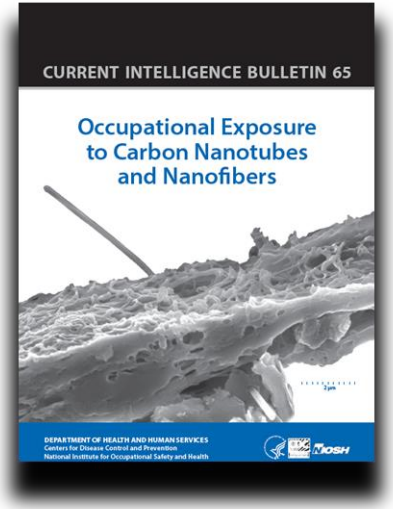
Dustiness

- Propensity of bulk material to release particles in response to mechanical stimulus
- Used to rank bulk materials / powders
- Requested property that will have to be measured for REACH dossier (Amended REACH annex)
- Conventional dustiness methods
  - EN15051: Health related dustiness mass fraction (e.g. respirable, thoracic, inhalable)
- Measurement of dustiness of bulk materials that contain or release respirable NOAA or other respirable particles.
  - EN 17199-4:2019: Dustiness number index



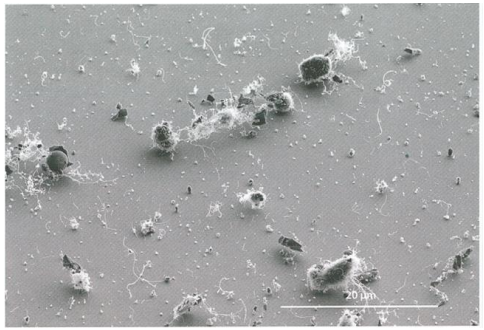
Current debate - Metrics and Workplace Exposure Limits

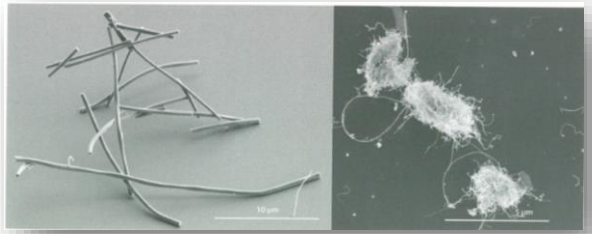
- UK: No specific WEL
- UK WEL for carbon black (3.5 mg/m3) not appropriate for CNTs
- Substances classified as hazardous substances in their non-nanoscale form will have substance-specific WELs (respirable or inhalable)
- CNTs: WEL of 1 µg/m^3 elemental carbon (NIOSH recommendation)
- TiO_2: WELs of 2.4 mg/m^3 for fine TiO_2 and 0.3 mg/m^3 for ultrafine (NIOSH recommendation)



- Metrics: Mass, number or surface area?
- Fibres: WEL based on number (f/ml)
- Diesel: PM, mass based elemental carbon, number

Current debates - CNTs





Photos from Nanovalid. Safe handling of nanomaterials and other advanced materials at workplaces. Baua: (2015)

- Should we count?
- What should be counted and how?
- What properties should we measure? Rigidity?
- New pre-normative research on counting rules for CNTs (workplace) to start soon (CEN TC 137 WG3)

Standardisation

Why is definition important?

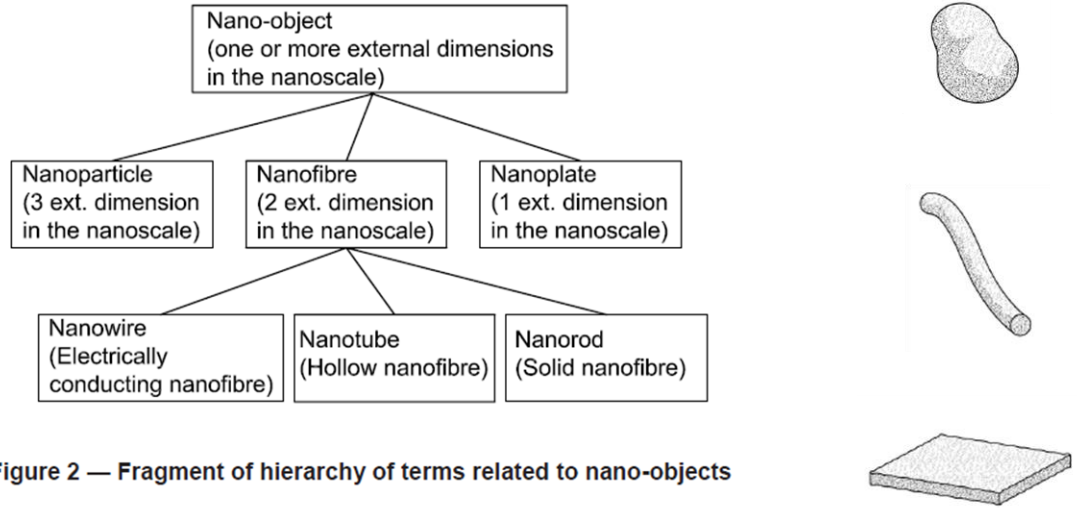
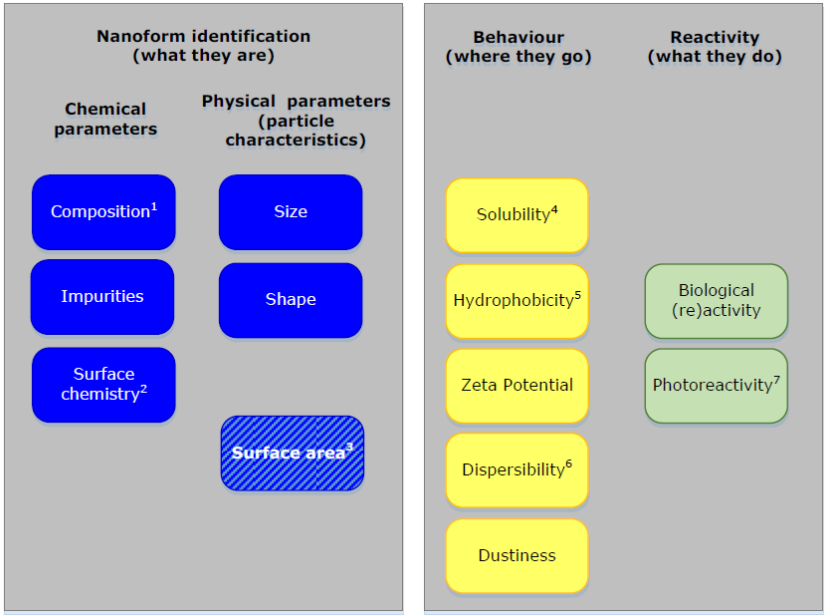


Figure 2 — Fragment of hierarchy of terms related to nano-objects

- Nano-object: material with one, two or three external dimensions in the nanoscale

ISO CEN TS 27687:2009 *Incorporating Corrigendum July 2015*. Nanotechnologies – Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate

Registration of nanoform



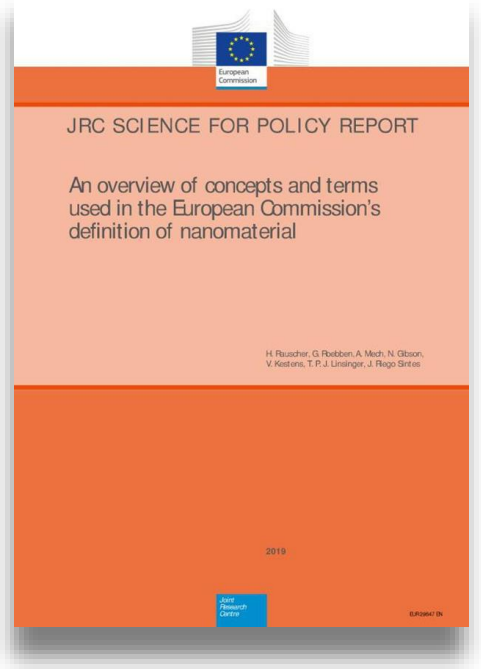
- Particle size distribution and number fraction
- Surface chemistry: surface functionalization or treatment
- Shape, aspect ratio, assembly structure, crystallinity

- ECHA: Guidance on information requirements and chemical safety assessment. Appendix R.6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals. V 1.0. May 2017
- ECHA: Appendix for nanoforms applicable to the Guidance on Registration and substance identification

- **But measurement challenges!**

EU definition of nanomaterial

- A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.
- … the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.
- … fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

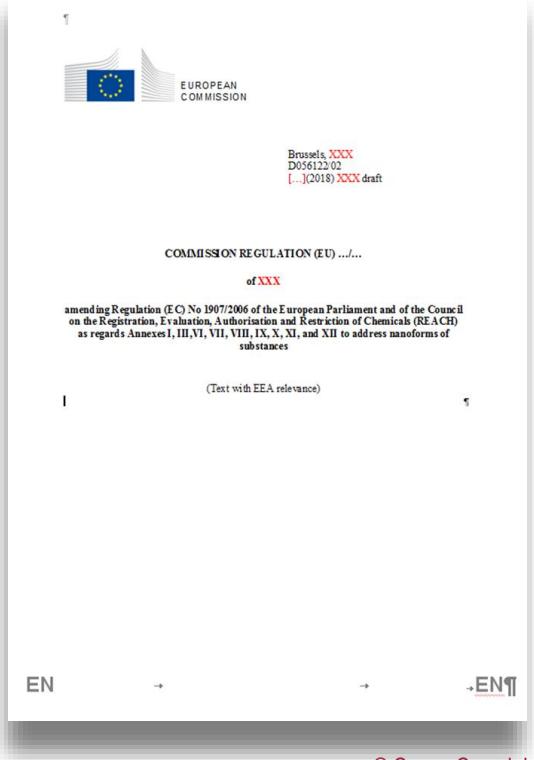


Legal duty

- Control of Substances Hazardous to Health (**COSHH**) Regulations
- **REACH** European Union Regulation concerning the Registration, Evaluation, Authorisation and restriction of Chemicals.
- **CLP** European Union Regulation concening the Classification, Labelling and Packaging of Substances and Mixtures the CLP
- Dangerous Substances and Explosive Atmospheres (**DSEAR**) Regulations
- Other EU regulations: Cosmetics, Novel Food, Biocidal Products

REACH

- Amended REACH annexes will apply from 1 Jan 2020
- Registration (manufacturers and importers) for quantities of 1 tonne per year or more
- Specify information required for the nanoform of a registered substance. It includes physicochemical properties and conditions to consider when carrying out toxicological or eco-toxicological tests.
- Possible to group nanoforms or set of nanoforms with similar characteristics.
- Similarity in molecular structure cannot serve as justification for application of grouping



EUROPEAN COMMISSION

Brussels, XXX
D056122/02
[…](2018) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

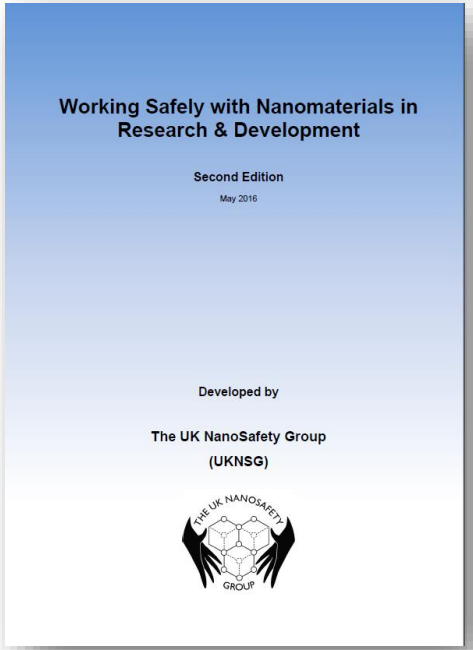
amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances

(Text with EEA relevance)

EN → → EN

UK NanoSafety Group

- Sensible guidance for those working with nanomaterials and needing to identify suitable control measures based on an understanding of the potential hazard status and risk factors
- UK NanoSafety Group Contributors:
  - Higher Education and Research Councils: University of Southampton; University of Bristol; University of Cambridge; Medical Research Council; University of Glasgow; University of Strathclyde
  - IOM
  - HSE and HSE SD
- Chairman: Dr David Kinnison, University of Southampton

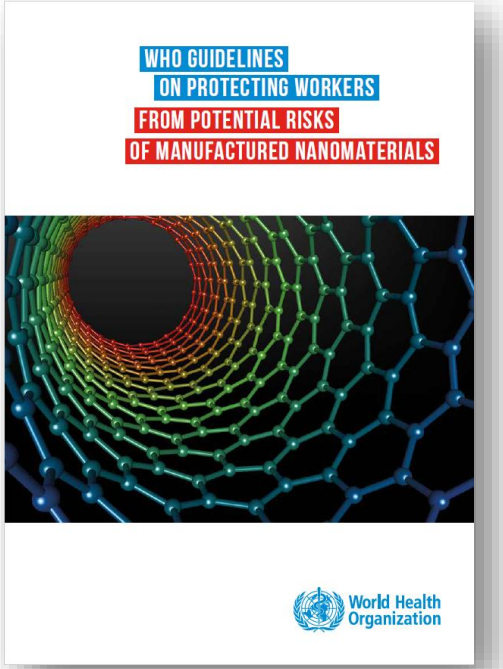


Waste guidelines

- Development of a technical specification: Guidelines for the management and disposal of waste from the manufacturing and processing of manufactured nano-objects (CEN mandate / CEN TC 352)
- Lead by HSE SD
- Developed by CEN/TC 352 committee members from Czech Republic, France, Germany, Italy, Portugal, UK, Switzerland and observer organisations (ECOS and NIA)
- Work funded by the European Commission and managed by AFNOR

WHO guidelines

- WHO recognises that: ”These guidelines significantly contribute to actions at the workplace as laid out by WHO Resolution WHA 60.26 on the Global Plan Action for worker’s health”
- Guidelines developed with the aim to protect workers from potential risks of MNMs
- Recommendations intended to help policy-makers and occupational health professionals in making decisions for safe work with MNMs. Also intended to support workers and employers



Summary

- No single measure of toxic potency can be attributed to all nanoparticles as not all nanoparticles are toxic nor equally hazardous
- Legislation of nanomaterials in the EU
- Uncertainties and knowledge gaps
- Measurement and testing challenges
- Practical measurement strategies and testing methodologies being developed
- Importance of standardisation

- **Nanotechnology offers commercial and societal benefits as long as we undertake this safely**

Thank you for listening

Questions?

Delphine.bard@hse.gov.uk

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Environmental, Safety & Health Conference 2019

Afternoon Break

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Insurance Responses to Changes in Environmental Risks

- Key Case Studies
- Env Risk and Insurance
- Aren't we insured already?
- Can we insure it?

June 2019

Duncan Spencer
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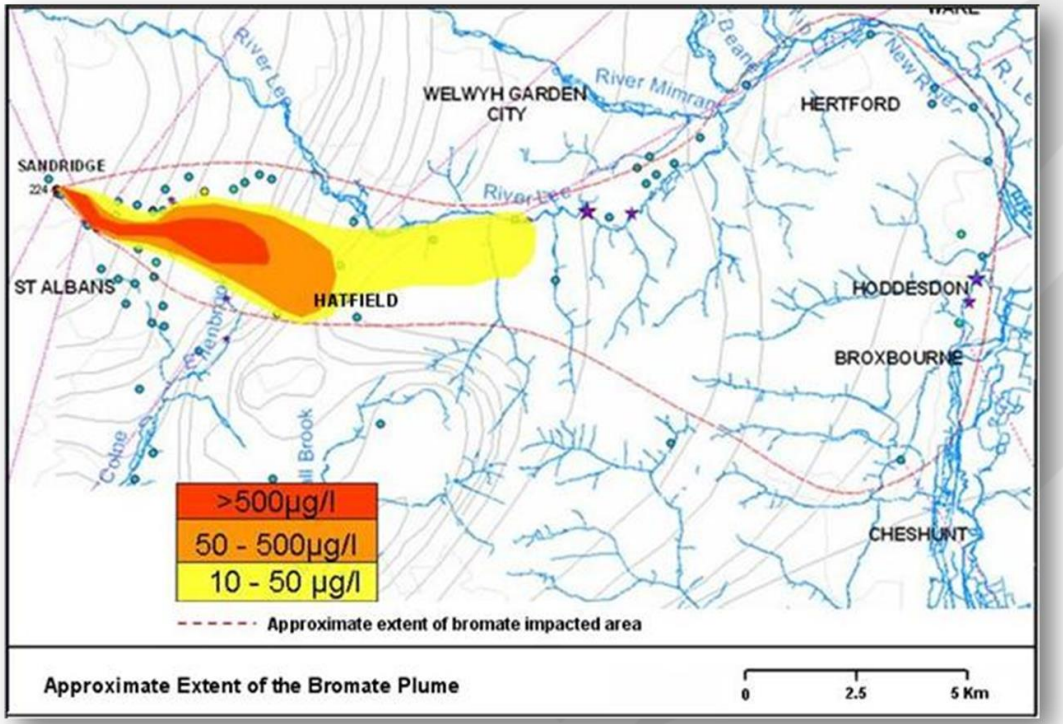
07825 884 222

Sandridge 2000 to 2019



- Chemical Works to 1980 (Redland Predecessor)
- Remains fallow 1983 to 1987
- Houses built by Crest with full planning
- Ground water pollution identified in 2000
- Crest and Redland accept responsibility 2010
- Civil Action ongoing

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Corby Steel Works 1986 to 2009

The Daily Telegraph

Thursday, July 30, 2009 BRITAIN'S BEST-SELLING QUALITY DAILY No 47,948 90p

'Worst child poisoning case since thalidomide'

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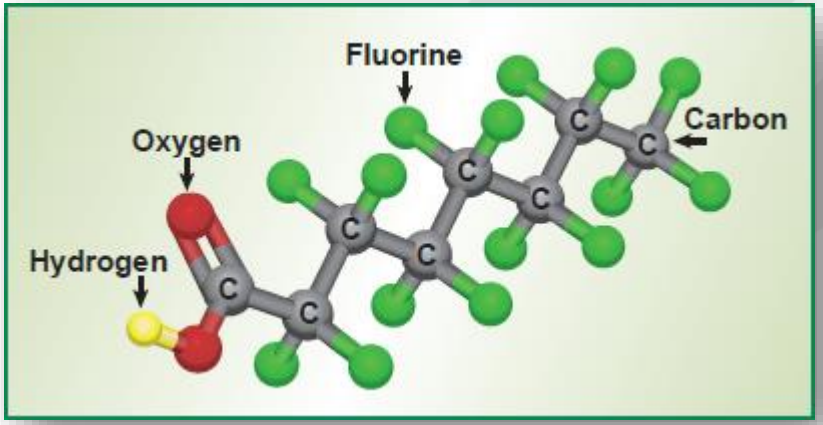
PFAS

Group of man-made chemicals that includes PFOA, PFOS, GenX, and many other chemicals.

PFAS have been manufactured since the 1940s.

Very persistent in the environment and in the human body – they don't break down and they can accumulate over time.



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PFAS Source and Impact

Food - packaging and growing media

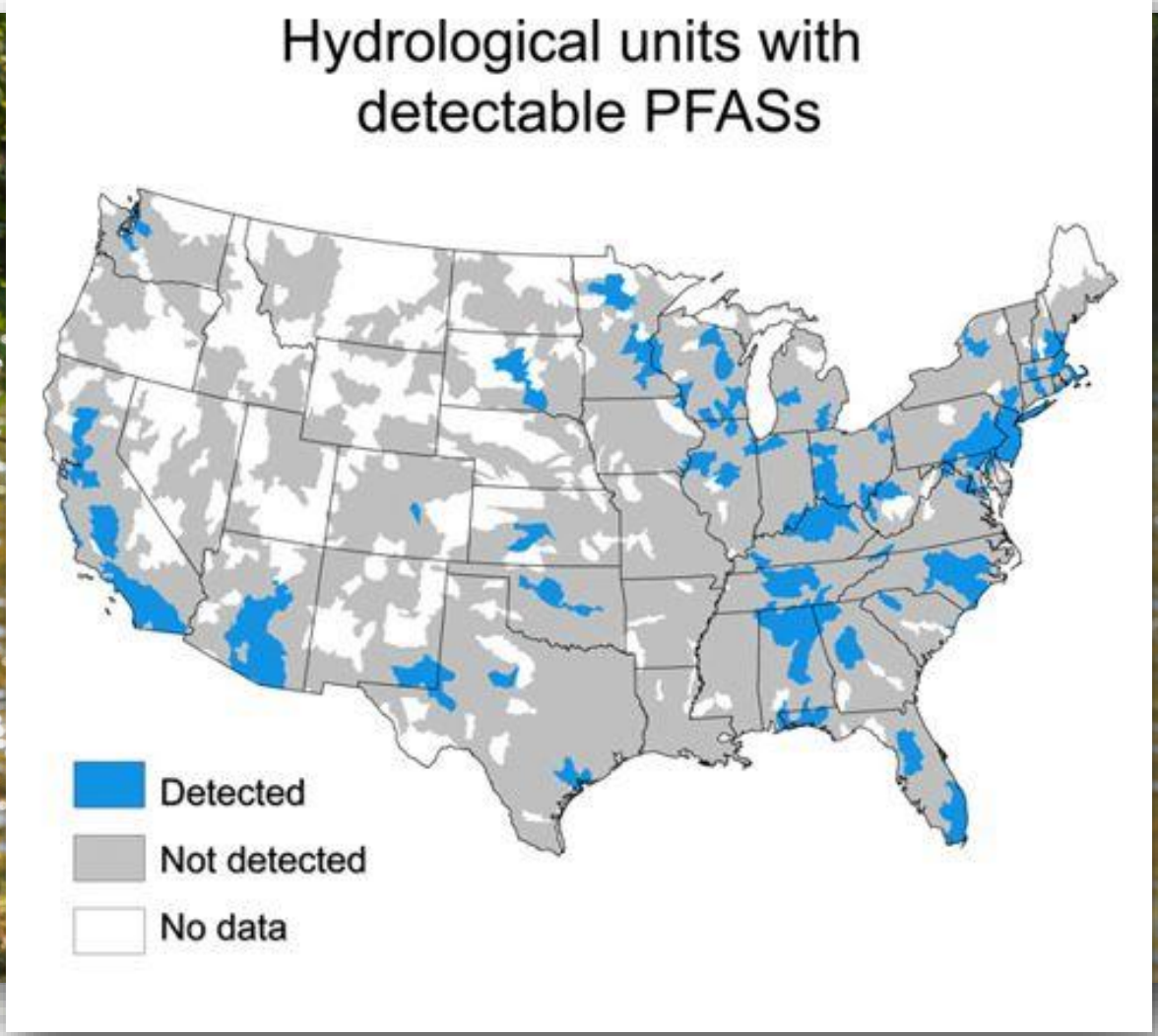
Commercial household products, stain- and water-repellent fabrics, nonstick products (e.g., Teflon), polishes, waxes, paints, cleaning products, and fire-fighting foams

Workplace - production facilities or industries (e.g., chrome plating, electronics manufacturing or oil recovery)

Drinking water - , typically localized and associated with a specific facility

- Reproductive and developmental impact.
- Liver and kidney, and immunological effects in laboratory animals.
- Caused tumors in animal studies.
- Increased cholesterol levels.
- Infant birth weights.
- Effects on the immune system.
- Cancer (for PFOA).
- Thyroid hormone disruption (for PFOS).

Ex



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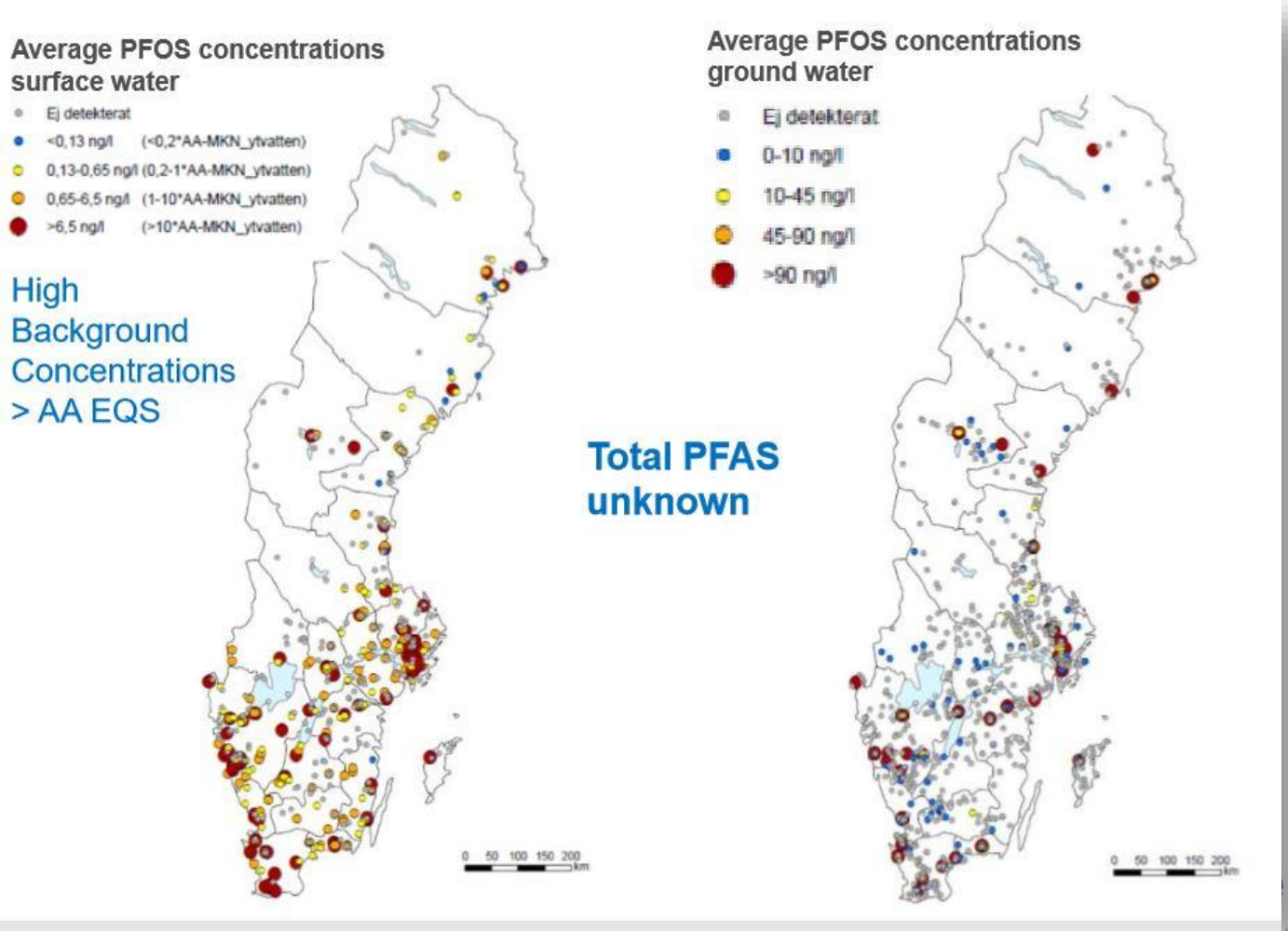

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December 2005 - Buncefield Oil Depot, Hemel Hempstead, UK - one of the largest fires in peacetime Europe

40 million litres of PFOS-based foam used
Over 20 Ml of contaminated fire water still to be treated and disposed of
PFOS concentration ca. 1.2 mg/l

Photos: Royal Chiltern Air Support Unit

Liability for PFAS

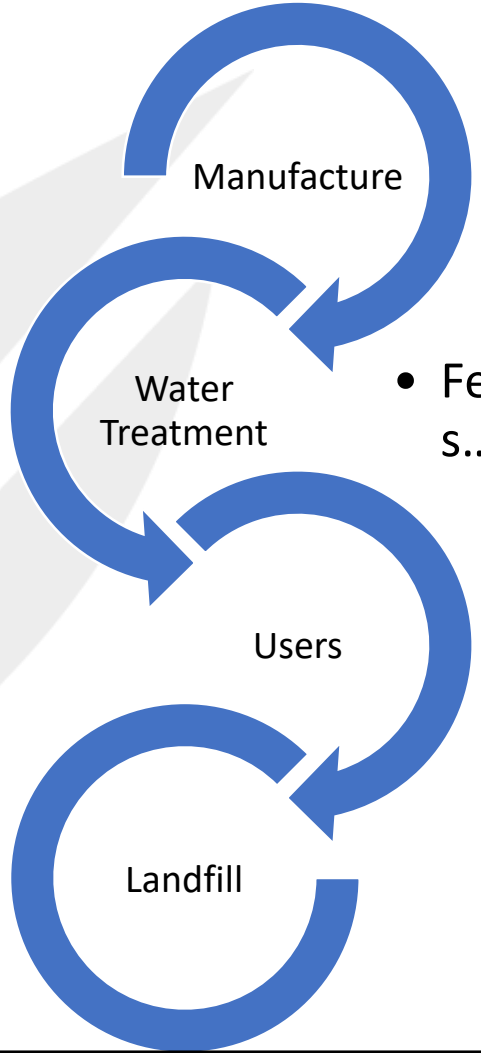
LANDMARK CASES….

2013 - State of Minnesota

Sued 3M for $5Bn – Settled at $850M

2017 - Residents at Parkersburg

Settled with DuPont - $671M



- Fertilisers…

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Observations

- Publicity for pollution seems to miss the mark…
- Actual risks already exist
- Have been known about since the 1980s and 90s
- Insurance industry has been responding…

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The Role of Insurance in Environmental Risk

Insurance Defined as:

- *"An arrangement by which a company or the state undertakes to provide a guarantee of compensation for specified loss … in return for payment of a specified premium."*

However:

- Environmental risk can be very large – and so difficult to price

SO:

- Insurers protect themselves by reducing cover for "pollution"

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Public Liability and Pollution

Extent of Cover

- If, as a result of **your business**, any party brings a claim against **you** for:
  - **bodily injury**, other than **abuse or molestation**, or **property damage** occurring during the **period of insurance**;
  - **personal injury** or **denial of access** committed during the **period of insurance**,
- **we** will indemnify **you** against the sums **you** have to pay as compensation.

Exclusion

- any **bodily injury** or **property damage** directly or indirectly caused by **pollution**; unless caused by a sudden, identifiable, unintended and unexpected incident which occurs in its entirety at a specific time and place during the **period of insurance**;

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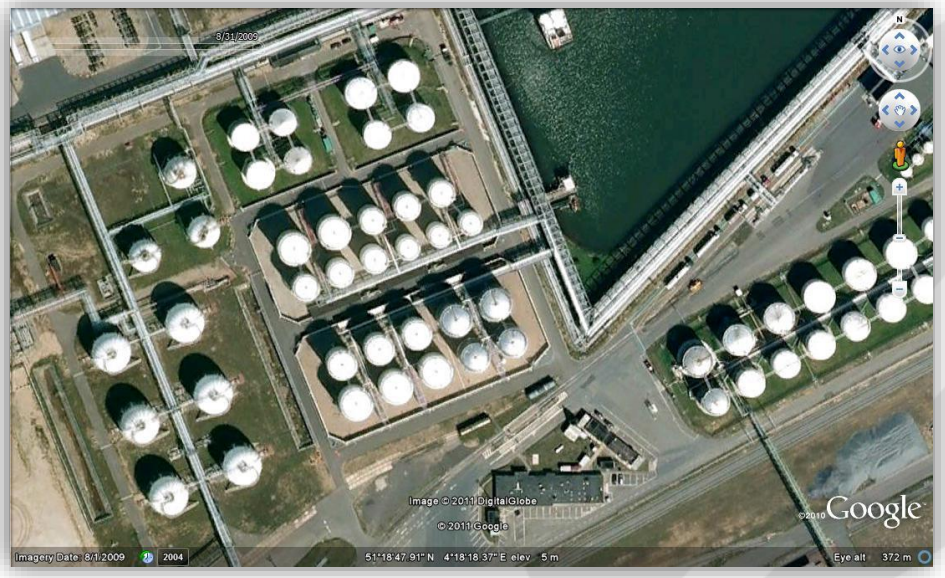
Aren’t we already insured?

Bartoline



Rotterdam

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Why is this?

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In Summary….

Does the liability Exist?

- YES

Does Public Liability insurance Respond?

- NO
- Unless it's a "sudden" event
- And it affects a third party…

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Can we insure against this liability?

Development Sites or Acquisition

Site Pollution Liability

- Cover for pollution that commenced *before* today

Contractors Pollution Liability

- Cover for pollution caused or made worse by development works

Maximum term: 10 years, maybe 15

Limits: £30M readily available

Operational Facilities

Operational Pollution Liability

- Cover for pollution that commenced *after* today

Contractors Pollution Liability

- Work on third party sites

Maximum term: Annual, maybe 5

Limits: £50M readily available

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In Conclusion

- Environmental Risk can be significant
- Ways of managing the risk create opportunities
- Insurance is a useful tool
- Needs to be used in conjunction with a reasonable DD process

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Q&A