REACH_MANOMATERIALI E MICROPLASTICHE

Udine 12 dicembre 2019

NANOMATERIALI
I RISCHI PER LA SALUTE UMANA

Francesca Larese Filon

UCO Medicina del Lavoro – Università di Trieste

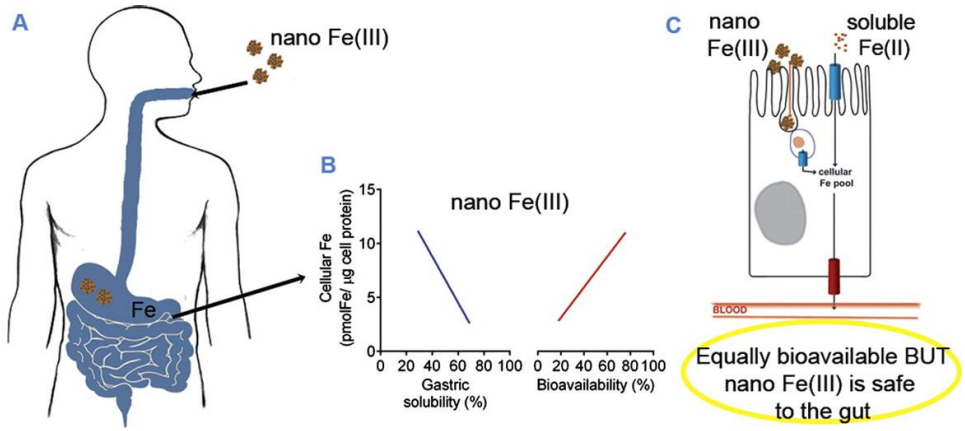
REGIONE AUTONOMA FRIULI VENEZIA GIULIA

Gruppo Tecnico Interregionale

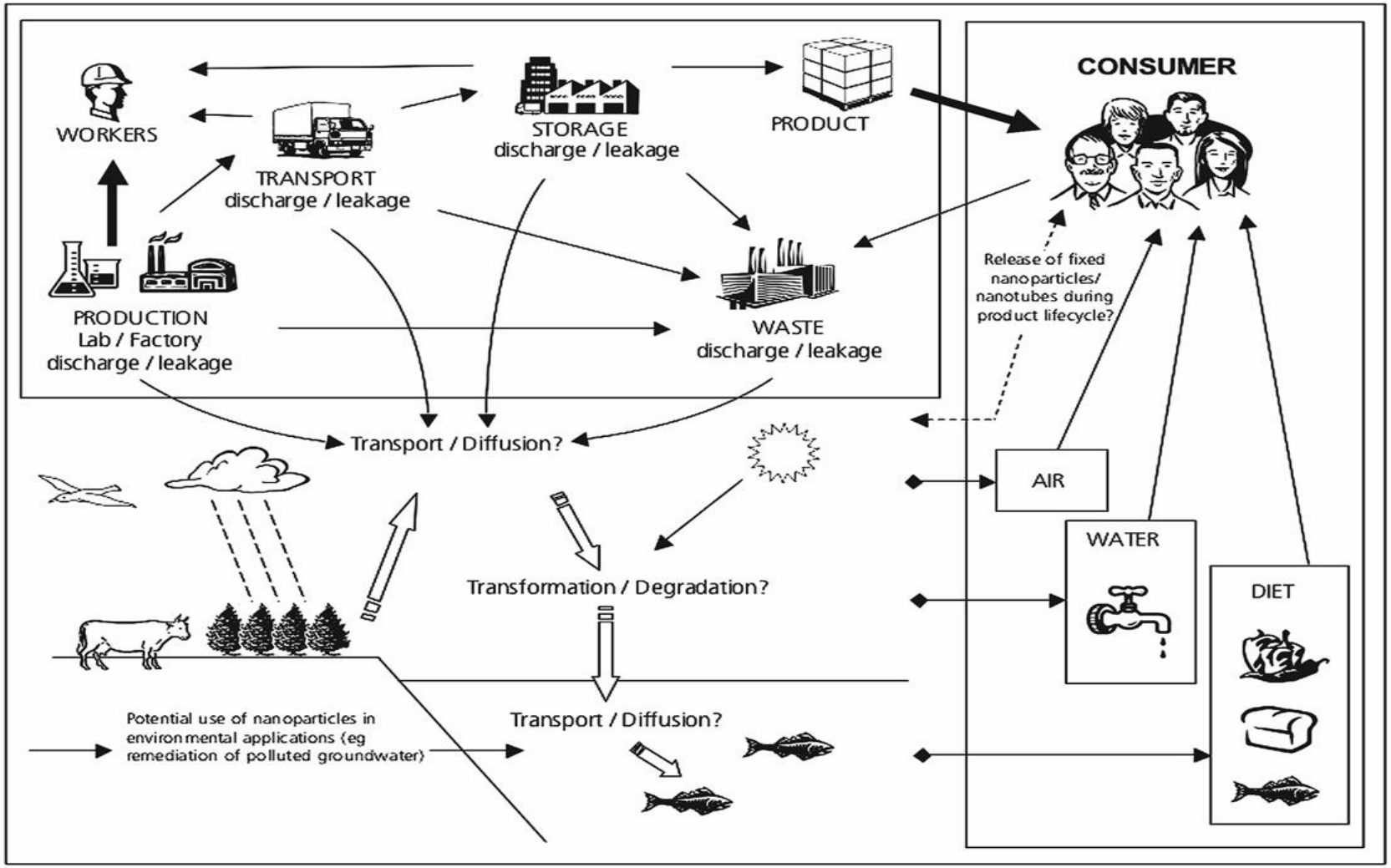
CLP REACH

Rischi per la salute umana

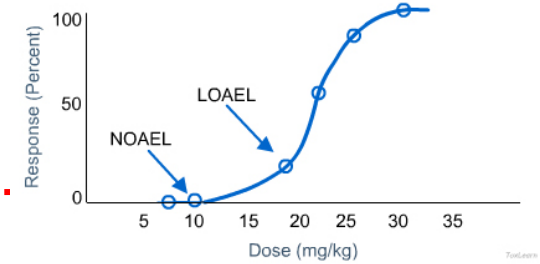
- Produttori
- Lavoratori
- Utilizzatori (cosmetici, oggetti, alimenti)
- Addetti allo smaltimento
- Diffusione nell'ambiente



Rischi per la salute umana

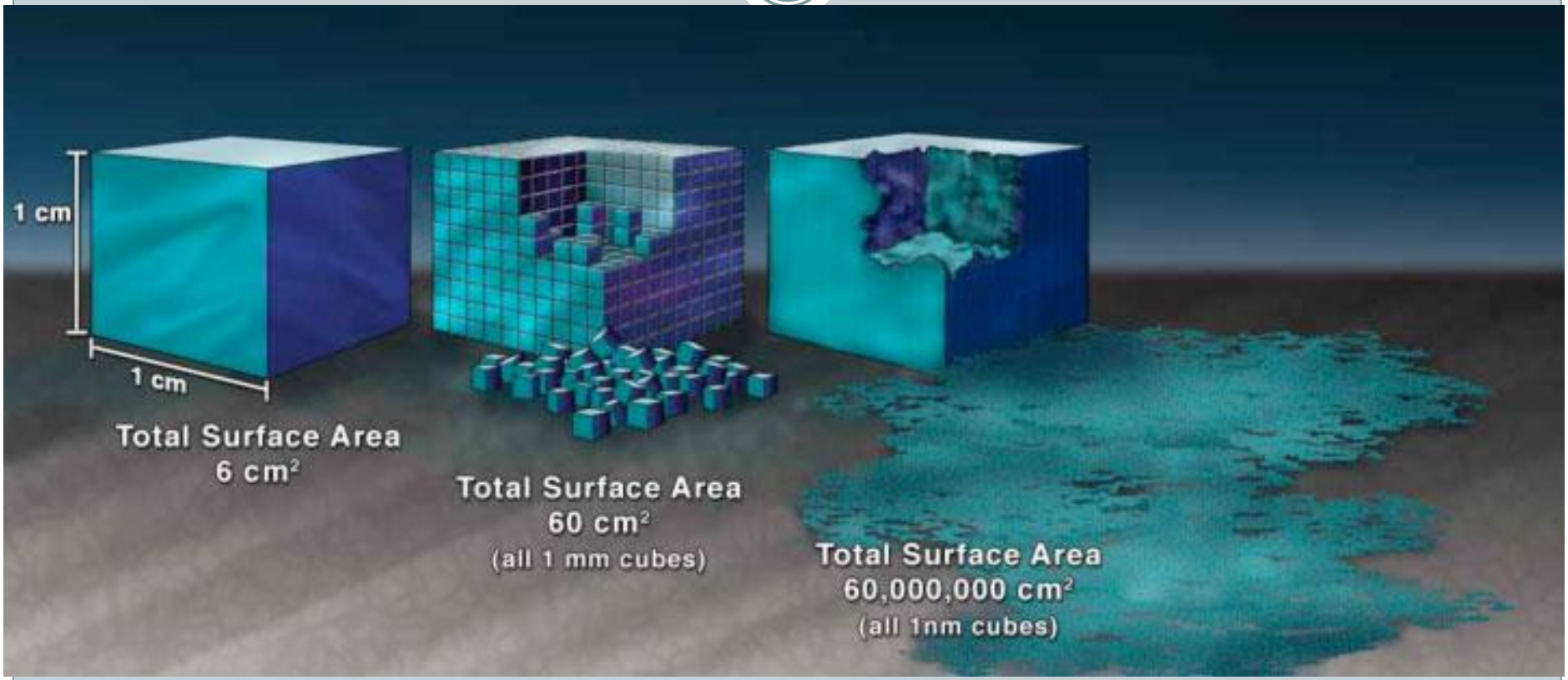


Identificazione del pericolo	· C'è ragione di credere che i NM siano pericolosi?
Caratterizzazione del pericolo	· In che modo e in che condizioni i NM possono essere pericolosi?
Valutazione dell'esposizione	· Quali sono i livelli e le modalità di esposizione a NM?
Caratterizzazione del rischio	· I NM sono rischiosi? · Ci sarà esposizione?
Gestione del rischio	· Sviluppare misure di prevenzione e protezione per ridurre l'esposizione



Da Cavallo DM Insubria

Aspetti cruciali



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Riediker *et al. Particle and Fibre Toxicology* (2019) 16:19
https://doi.org/10.1186/s12989-019-0302-8

Particle and Fibre Toxicology

REVIEW Open Access

Particle toxicology and health - where are we?

Michael Riediker[1*], Daniele Zink[2], Wolfgang Kreyling[3], Günter Oberdörster[4], Alison Elder[4], Uschi Graham[5], Iseult Lynch[6], Albert Duschl[7], Gaku Ichihara[8], Sahoko Ichihara[9], Takahiro Kobayashi[10], Naomi Hisanaga[11], Masakazu Umezawa[8], Tsun-Jen Cheng[12], Richard Handy[13], Mary Gulumian[14], Sally Tinkle[15] and Flemming Cassee[16,17]

Esposizione

- Via inalatoria
- Via cutanea
- Via digestiva

Grande superficie
Elevata reattività

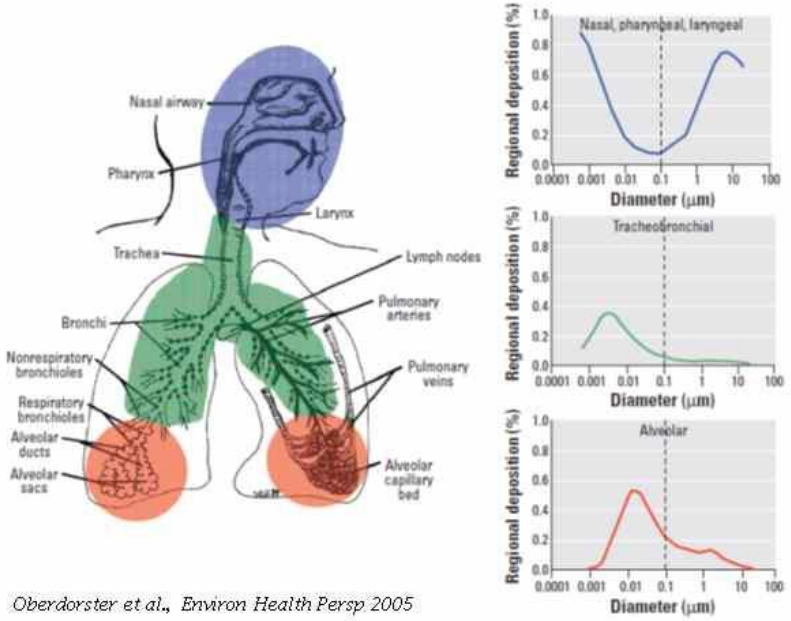
Esposizione per via inalatoria a NM e NP

Grande concentrazione numerica e ampia area superficiale per unità di volume (o massa)

→ **Reattività**
(ROS; maggior numero di atomi o molecole superficiali per unità di massa)

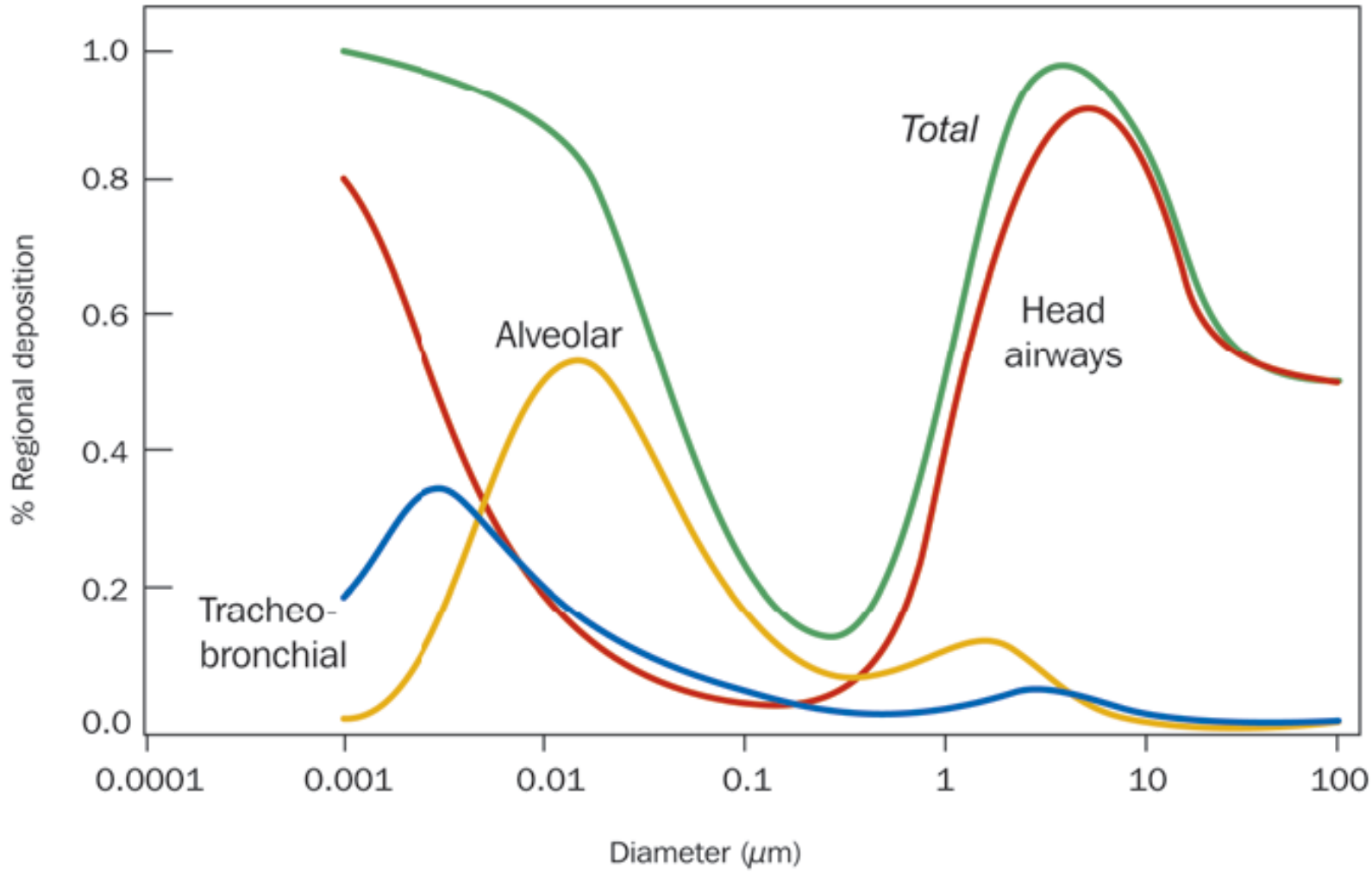
Deposizione nel tratto respiratorio

→ **Osservata in tutte le regioni del tratto respiratorio** (*diffusione*)



Oberdorster et al., Environ Health Persp 2005

Da Cavallo DM Università dell'Insubria

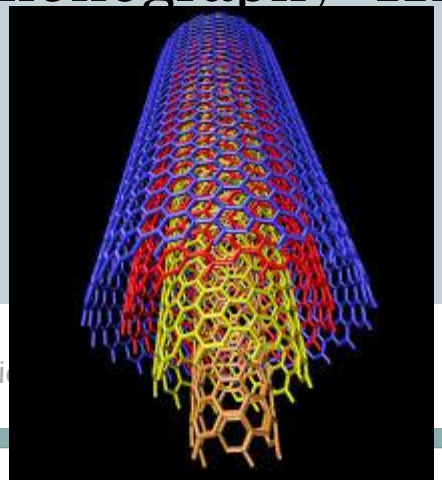


Da ICRP 1996: deposizione di particelle nel tratto respiratorio

Carbon nanotubes

- Low clearance suggesting an asbestos-like effect demonstrated on animals with pulmonary inflammation, damage, fibrogenicity and tumorigenesis.

- Recently, the International Agency for Research on Cancer has classified multi walled carbon nanotubes 7 (Mitsui Ltd., Japan) to a Category 2B: **possibly carcinogenic to humans** (Grosse et al. 2014) in IARC monography 111 “Some Nanomaterials and Some Fibres".



Esposizione per via inalatoria

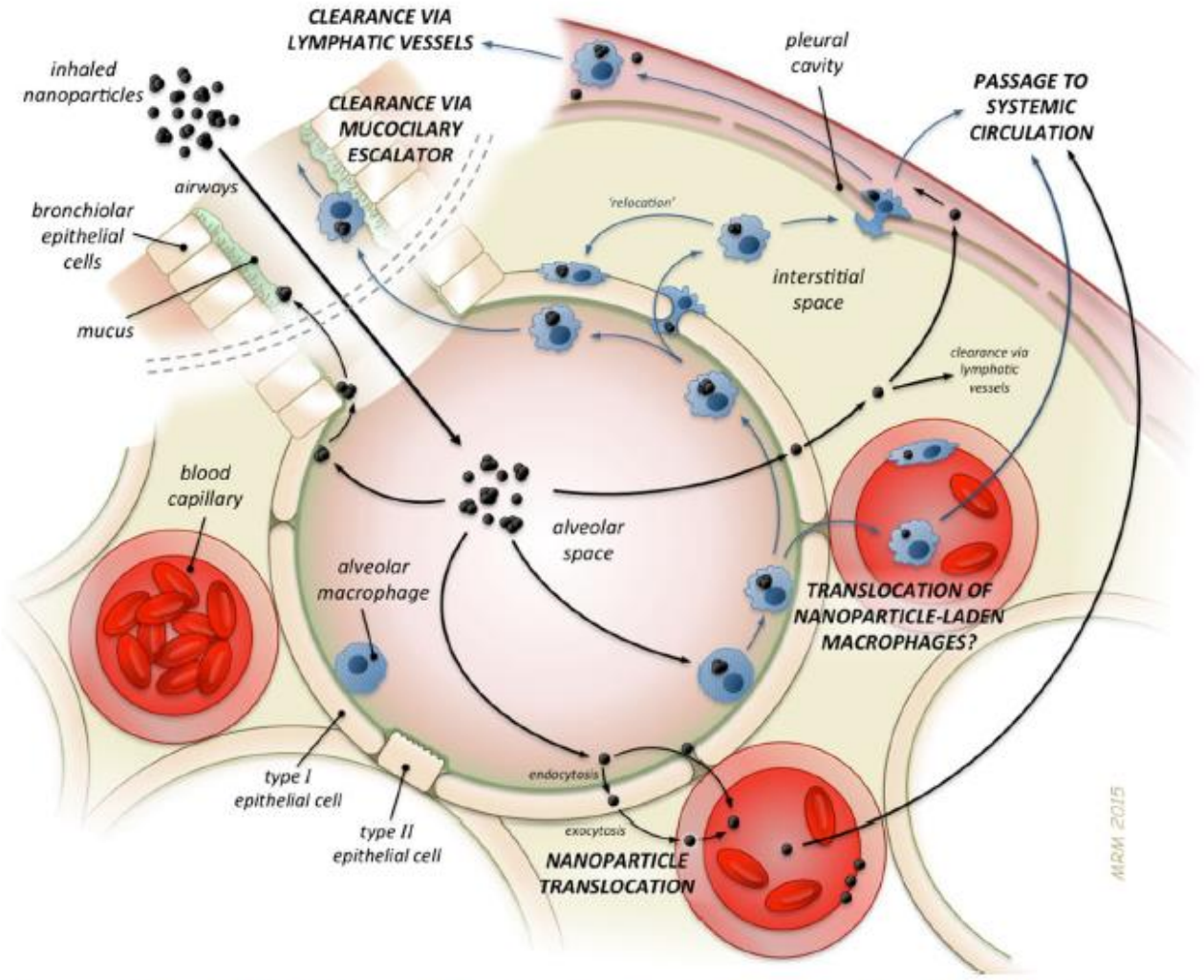
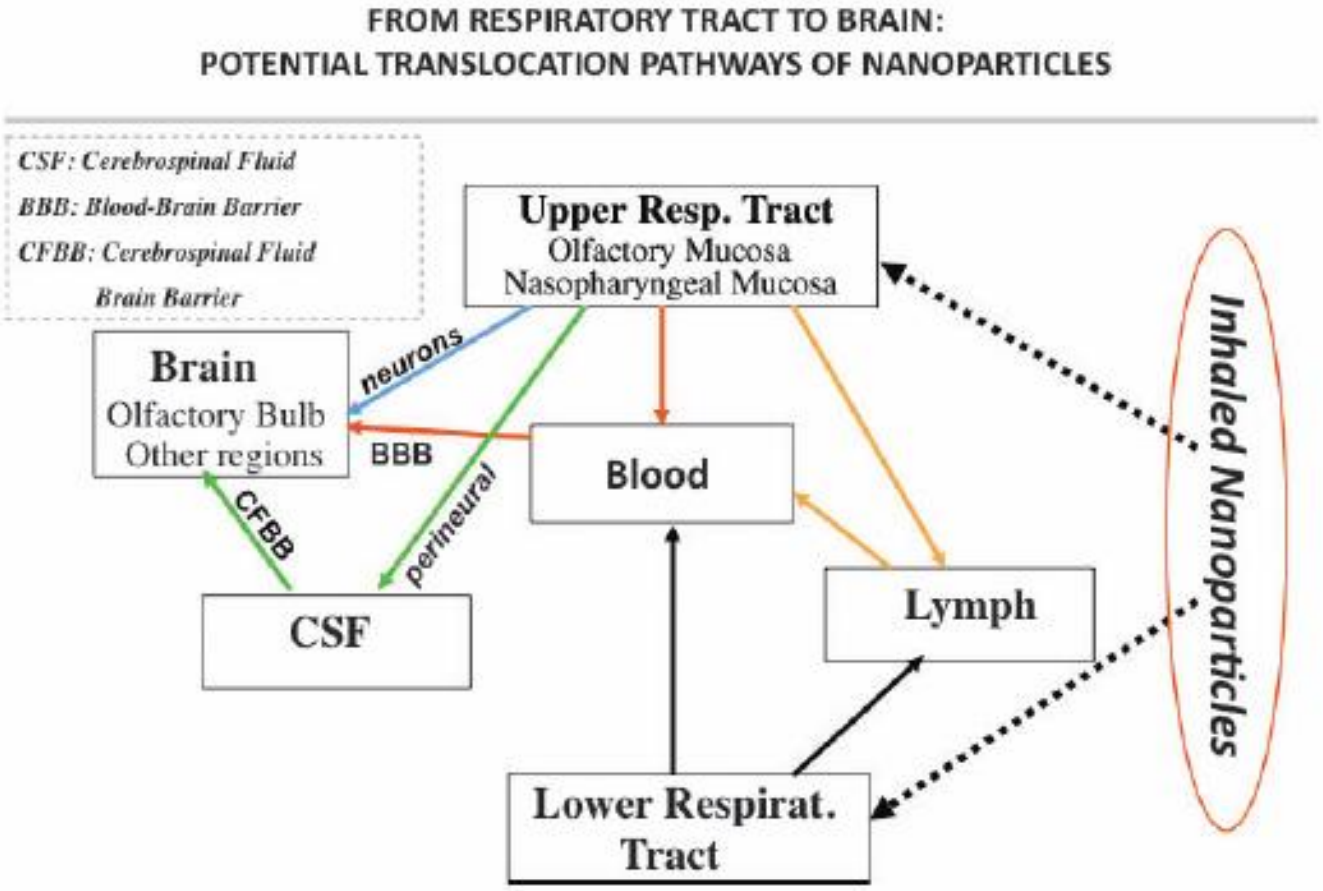


Fig. 1 Overview on different types of NP's translocation and clearance in the lungs. Artwork by Mark Miller, reproduced with permission from [14].

Riedker et al. 2019



Oberdoster, 2009

Dopo istillazione intratracheale

Frazione di
Biossido di titanio
Nano rilevato nei vari
Organi
dopo 1, 6 e 28 giorni

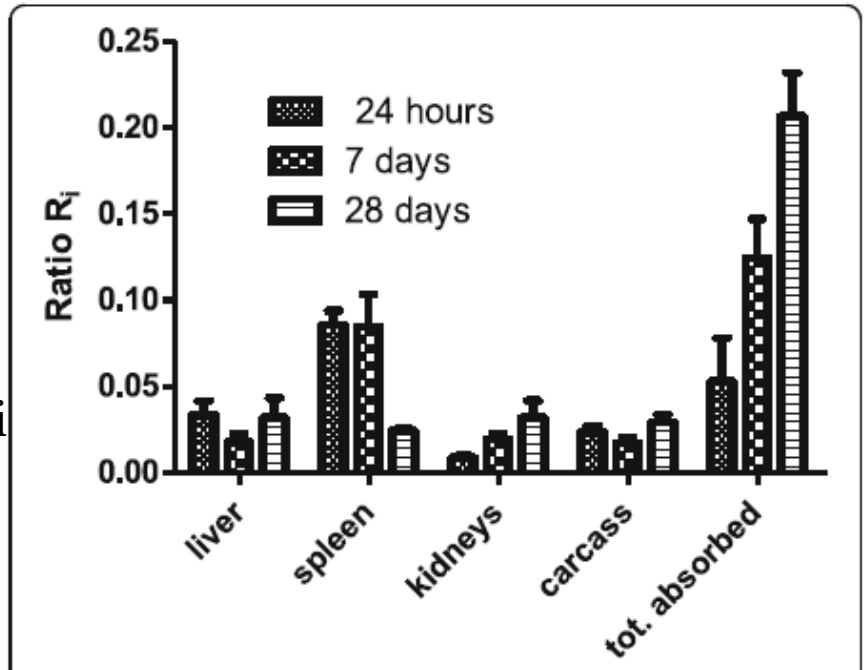
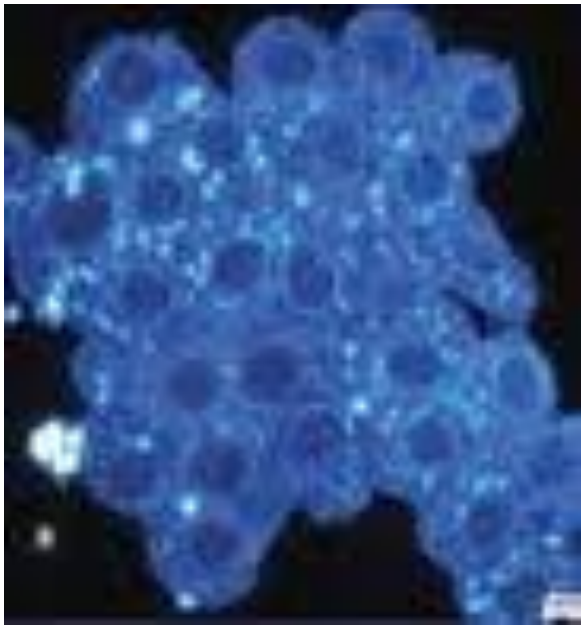


Fig. 3 The ratios R_i represent the fractions of $TiO_2$2NP present in liver, spleen, kidneys and carcass (without organs) and the integral sum of all absorbed fractions determined after IT-instillation that have been absorbed through the GIT relative to the sum of gut-absorbed and ABB-translocated TiO_2NP after 1, 7 and 28 days. Mean ± SEM of n=4 rats at each time point.

Riedeker et al 2019

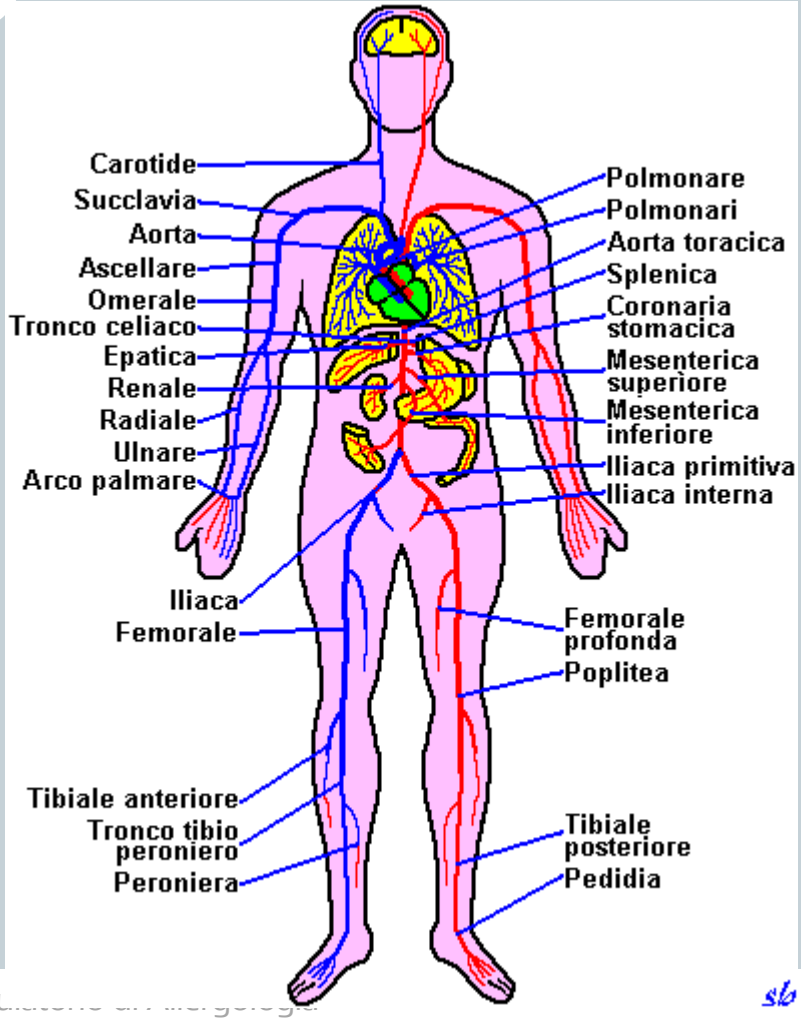
Inhal Toxicol. 2009 Jul;21 Suppl 1:83-91.
Subacute intratracheal exposure of rats to manganese nanoparticles: behavioral, electrophysiological, and general toxicological effects. Sárközi L et al.

Ratti esposti a Mn02 (23nm) da 2.63 a 5.26 mg Mn/kg per istillazione tracheale presentano Mn nel polmone e nel cervello



NPs exposure

- Translocation in blood barrier with increase risk of cardiovascular diseases (demonstrated in animals)
-



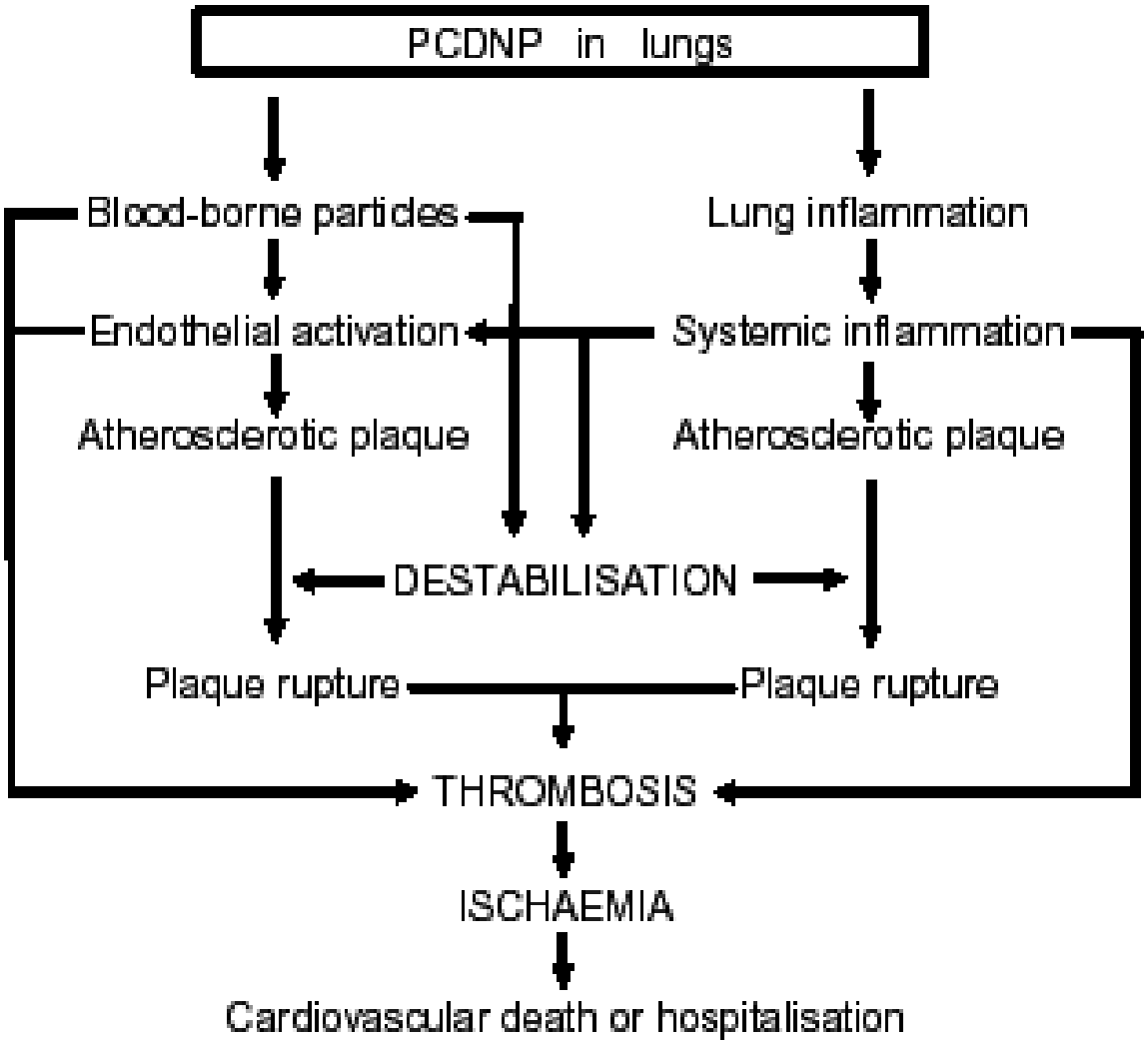


Figure 3. Some of the potential pathways for the action of NP on the cardiovascular system with special emphasis on coronary artery disease.

Donaldson, 2004

nline First, published on February 10, 2018 as 10.1136/oemed-2017-104796

ORIGINAL ARTICLE

Cardiovascular effects among workers exposed to multiwalled carbon nanotubes

Methods A cross-sectional study was performed among 22 workers of a company commercially producing MWCNTs (subdivided into lab personnel with low or high exposure and operators), and a gender and age-matched unexposed population (n=42). Exposure to MWCNTs and 12 cardiovascular markers were measured in participants' blood (phase I). In a subpopulation of 13 exposed workers and six unexposed workers, these measures were repeated after 5 months (phase II). We analysed associations between MWCNT exposure and biomarkers of cardiovascular risk, adjusted for age, body mass index, sex and smoking.

nline First, published on February 10, 2018 as 10.1136/oemed-2017-104796

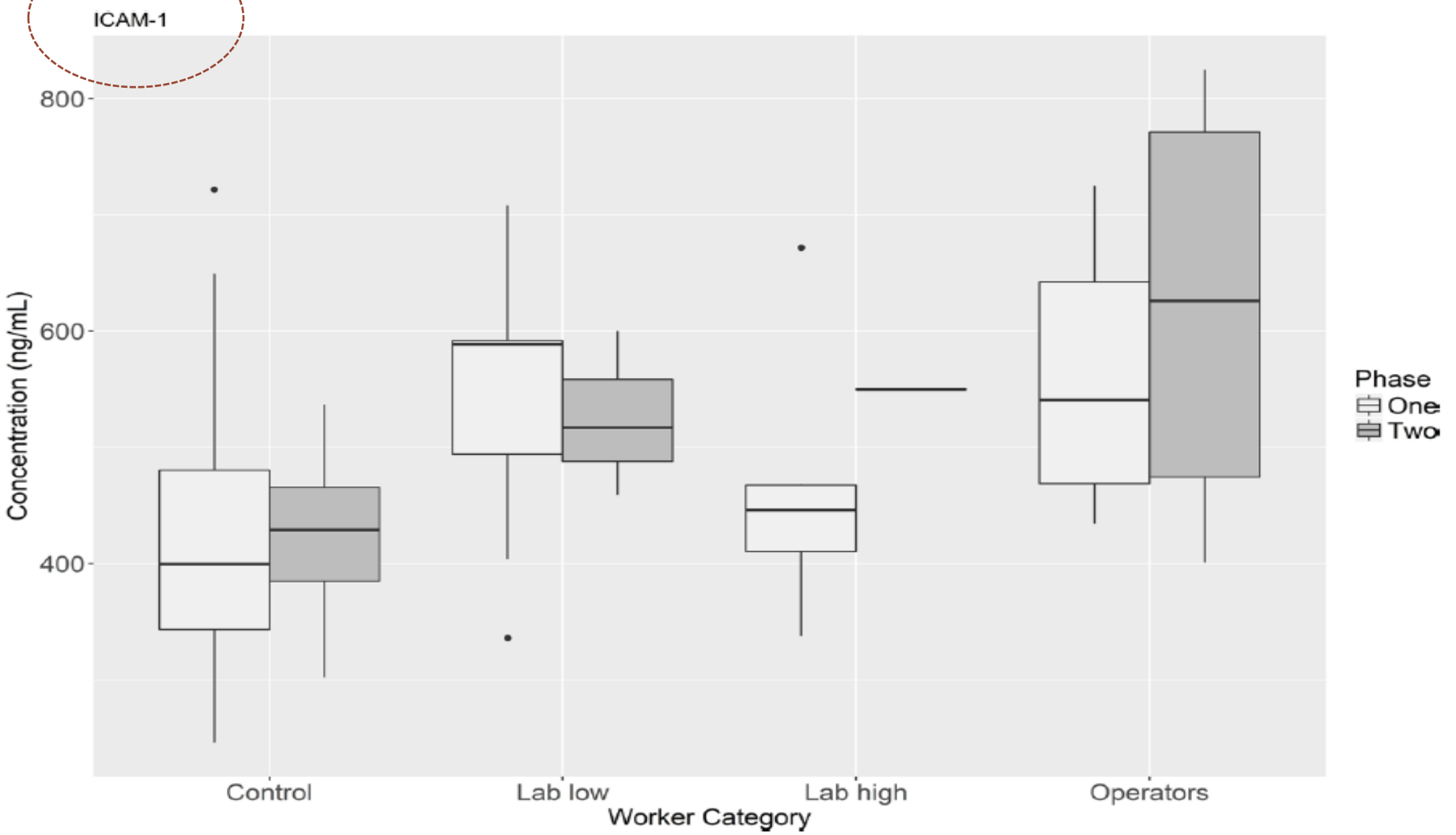


Figure 1 Boxplot showing the distribution of intercellular adhesion molecule-1 (ICAM-1) concentrations during phases I and II for every exposure category. Kruskal-Wallis rank-sum test P values were 4.60E-3 and 0.13, respectively for phases I and II. Wilcoxon rank-sum test P values for operators versus controls were 6.36E-3 for phase I and 0.04 for phase II.

nline First, published on February 10, 2018 as 10.1136/oemed-2017-104796

ORIGINAL ARTICLE

Cardiovascular effects among workers exposed to multiwalled carbon nanotubes

What are the new findings?

- Our results show associations between MWCNT exposure and ICAM-1, indicating endothelial activation and an increased inflammatory state in workers with MWCNT exposure.

Nanotoxicology. 2018 Jan 11:1-16. doi:

Cardiopulmonary effects induced by occupational exposure to titanium dioxide nanoparticles

- In packaging workshop, the total mass concentration of particles was 3.17 mg/m^3. The mass concentration of nanoparticles was 1.22 mg/m^3 accounting for 39% of the total mass.

- Lung damage markers (**SP-D (collectina polmonare**) and pulmonary function), cardiovascular disease markers **(VCAM-1, ICAM-1, LDL, and TC),** oxidative stress markers **(SOD and MDA),** and inflammation markers **(IL-8, IL-6, IL-1β, TNF-α, and IL-10)** were associated with occupational exposure to nano-TiO2.

- Among those markers, **SP-D** showed a time (dose)-response pattern within exposed workers.
- The data strongly suggest that nano-TiO_2 could contribute, at least in part, to the **cardiopulmonary effects observed in workers**. The studied markers and pulmonary function tests may be useful in health surveillance for workers exposed to nanomaterials.

Titania NPs

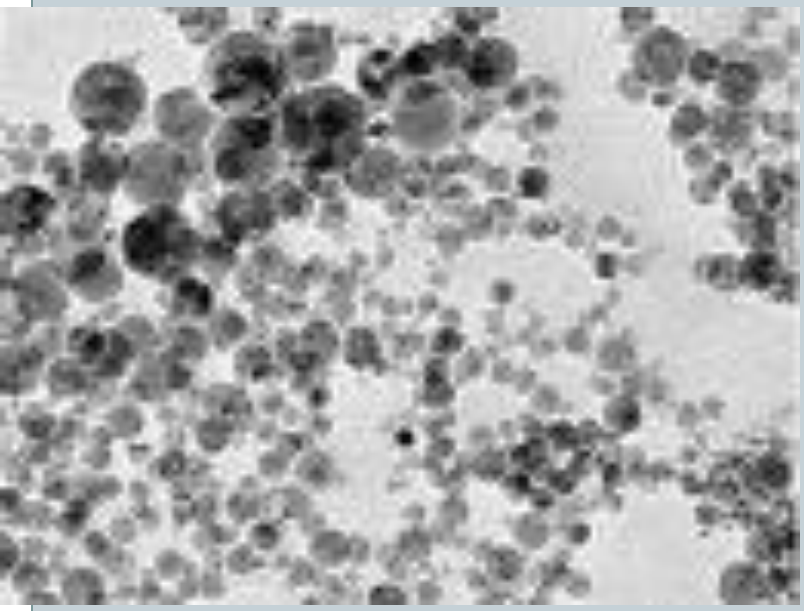
- Cheng et al. (2012) reported that a worker developed **bronchiolitis obliterans organizing pneumonia** after working for 3 months with polyester powder paint containing TiO_2 NPs.

- TiO2 dust released from mining process was classified as a Group 2B carcinogen by the IARC due to the possibility of it being carcinogenic to humans.

- TiO2 dust can cause respiratory tract cancer in mice (Hu et al, 2010; Lam et al, 2004) and lung cell injury with mutation and **fibrosis** in humans who work in these dusty environments (Hendren et al, 2011; Robichaud et al, 2009)

- …

Biossido di Titanio old studies



- Boffetta (2004) Indaga 15000 lavoratori esposti a Ti02 in varie industrie europee
  - Non eccesso di tumori al pomone
- Hext (2005) riporta due studi che evidenziano alterazione dei parametri ventilatori negli esposti (dati anni 80)

Scheepers *et al. Journal of Occupational Medicine and Toxicology* (2017) 12:33
DOI 10.1186/s12995-017-0180-7

Journal of Occupational Medicine and Toxicology

CASE REPORT Open Access

Pulmonary injury associated with spray of a water-based nano-sized waterproofing product: a case study

Paul T. J. Scheepers[1*], Lucie Masen-Poos[2], Frits G. B. G. J. van Rooy[3], Arné Oerlemans[1], Eline van Daalen[1,6], Robbert Cremers[1,7], Hera Lichtenbeld[4], Bonne Biesma[2], Jorid B. Sørli[5], Ismo K. Koponen[5], Søren Thor Larsen[5], Peder Wolkoff[5] and Asger W. Nørgaard[5]

Carbon black

- Carbon black (50-500 nm) exposed workers were studied in long term cohorts finding an increased risk for **lung cancer** (Sorathan 2001).

- Zhang et al. in 2014 demonstrated that nanoscale carbon black particles could be responsible for the **lung function reduction and pro-inflammatory cytokines secretion** in exposed workers.

Polyacrilate/silica NPs

- Polyacrilate NPs in a spray used in a small factory without exhaustion system caused severe **pleuropulmonary symptoms** in 7 young female Chinese workers leading to death in two of them (Song et al 2009 and 2011 to characterize **silica NPs** in coating).

Eur Respir J 2009; 34: 559–567
DOI: 10.1183/09031936.00178308

Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma

Y. Song*, X. Li# and X. Du*

Song Y, Li X, Wang L *et al.* Nanomaterials in humans: identification, characteristics, and potential damage. *Toxicol Pathol* 2011;**39:**841–849.

Eur Respir J 2009; 34: 559–567
DOI: 10.1183/09031936.00178308

Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma

Y. Song*, X. Li# and X. Du*

TABLE 1 Patients' characteristics

Case	Age yrs	Sex	Duration of exposure months	P_{O_2} kPa	Pleural effusion	Pericardial effusion	Bronchoscopy	Thoracoscopy	VATS	Outcome
1	29	Female	13	9.6	Great	Small	+	+	-	Died
2	47	Female	11	10.5	Great	None	+	+	-	Stable
3	18	Female	13	9.6	Great	Small	+	+	+	Stable
4	29	Female	12	11.6	Great	Small	+	-	-	Stable
5	19	Female	10	10.7	Great	Small	+	-	+	Died
6	35	Female	10	12.9	Great	Small	+	-	-	Stable
7	28	Female	5	12.9	Small	None	+	-	-	Stable

P_{O_2}: oxygen tension; VATS: video-assisted thoracic surgery. +: performed; -: not performed.

Schubauer-Berigan *et al. Particle and Fibre Toxicology* (2018) 15:22
https://doi.org/10.1186/s12989-018-0258-0

Particle and Fibre Toxicology

RESEARCH Open Access

Association of pulmonary, cardiovascular, and hematologic metrics with carbon nanotube and nanofiber exposure among U.S. workers: a cross-sectional study

Mary K. Schubauer-Berigan[1*], Matthew M. Dahm[1], Aaron Erdely[2], John D. Beard[1,3,5], M. Eileen Birch[4], Douglas E. Evans[4], Joseph E. Fernback[4], Robert R. Mercer[2], Stephen J. Bertke[1], Tracy Eye[2] and Marie A. de Perio[1]

108 lavoratori

Conclusions: Most health measures were not associated with CNT/F. The positive associations between CNT/F exposure and respiratory allergies, RHR, and hematocrit counts may not be causal and require examination in other studies.

RHT resting heart rate CNT/F carbonnanotubes, fibers

Schubauer-Berigan *et al. Particle and Fibre Toxicology* (2018) 15:22
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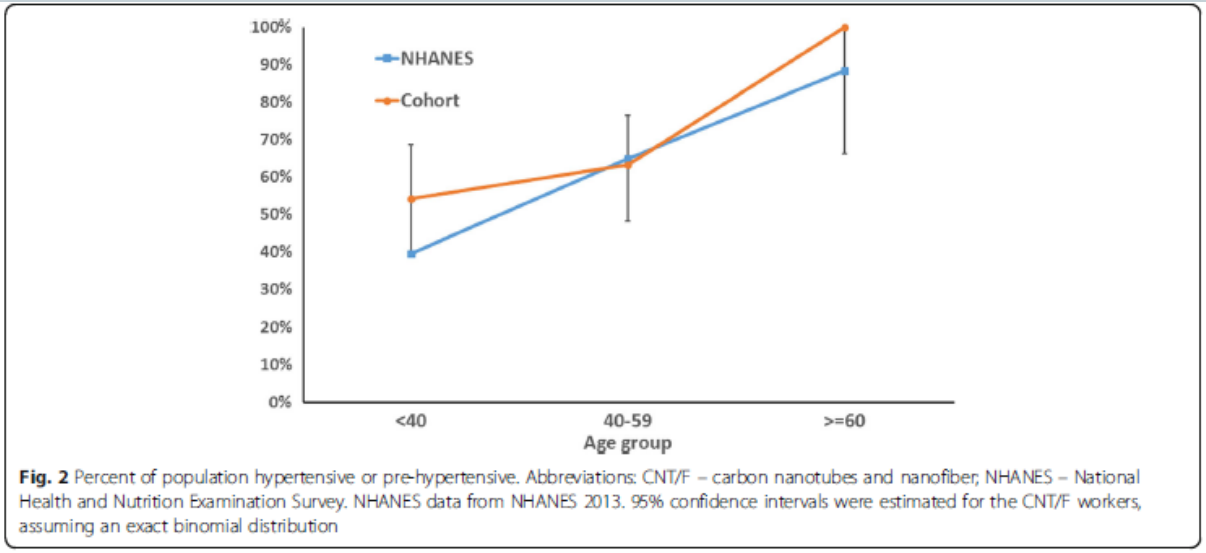

Fig. 2 Percent of population hypertensive or pre-hypertensive. Abbreviations: CNT/F – carbon nanotubes and nanofiber, NHANES – National Health and Nutrition Examination Survey. NHANES data from NHANES 2013. 95% confidence intervals were estimated for the CNT/F workers, assuming an exact binomial distribution

RHT r

Pulmonary hypofunction due to calcium carbonate nanomaterial exposure in occupational workers: a cross-sectional study.

Li G. et al. Nanotoxicology. 2018 Aug;12(6):571-585

- 28 lavoratori esposti vs non esposti
- Diminuzione dei parametri spirometrici negli esposti ma non correlati al livello dell'esposizione

Published in final edited form as:
Environ Int. 2018 July ; 116: 214–228. doi:10.1016/j.envint.2018.04.004.

Carbon nanotube and nanofiber exposure and sputum and blood biomarkers of early effect among U.S. workers

John D. Beard[a,b,1,*], Aaron Erdely[c], Matthew M. Dahm[b], Marie A. de Perio[b], M. Eileen Birch[d], Douglas E. Evans[d], Joseph E. Fernback[d], Tracy Eye[c], Vamsi Kodali[c], Robert R. Mercer[c], Stephen J. Bertke[b], and Mary K. Schubauer-Berigan[b]

108 lav

Results—We derived three sputum and nine blood biomarker factors that explained 78% and 67%, respectively, of the variation. After adjusting for potential confounders, inhalable EC and total inhalable CNT/F structures were associated with the most sputum and blood biomarkers, respectively. Biomarkers associated with at least three CNT/F metrics were 72 kDa type IV collagenase/matrix metalloproteinase-2 (MMP-2), interleukin-18, glutathione peroxidase (GPx), myeloperoxidase, and superoxide dismutase (SOD) in sputum and MMP-2, matrix metalloproteinase-9, metalloproteinase inhibitor 1/tissue inhibitor of metalloproteinases 1, 8-hydroxy-2′-deoxyguanosine, GPx, SOD, endothelin-1, fibrinogen, intercellular adhesion molecule 1, vascular cell adhesion protein 1, and von Willebrand factor in blood, although directions of associations were not always as expected.

Conclusions—Inhalable rather than respirable CNT/F was more consistently associated with fibrosis, inflammation, oxidative stress, and cardiovascular biomarkers.

Metal NPs

- Metal NPs can be dangerous for the release of toxic or sensitizing metals. Philips et al. in 2010 reported a case of a young man that died from adult **respiratory distress syndrome 13 days after exposure to nickel NPs sprayed onto** bushes for turbine bearings.

- Journeay & Goldman (2014) reported a case of a woman that developed **dermatitis and respiratory symptoms after the exposure to NiNPs without protection to prepare a** formulation.

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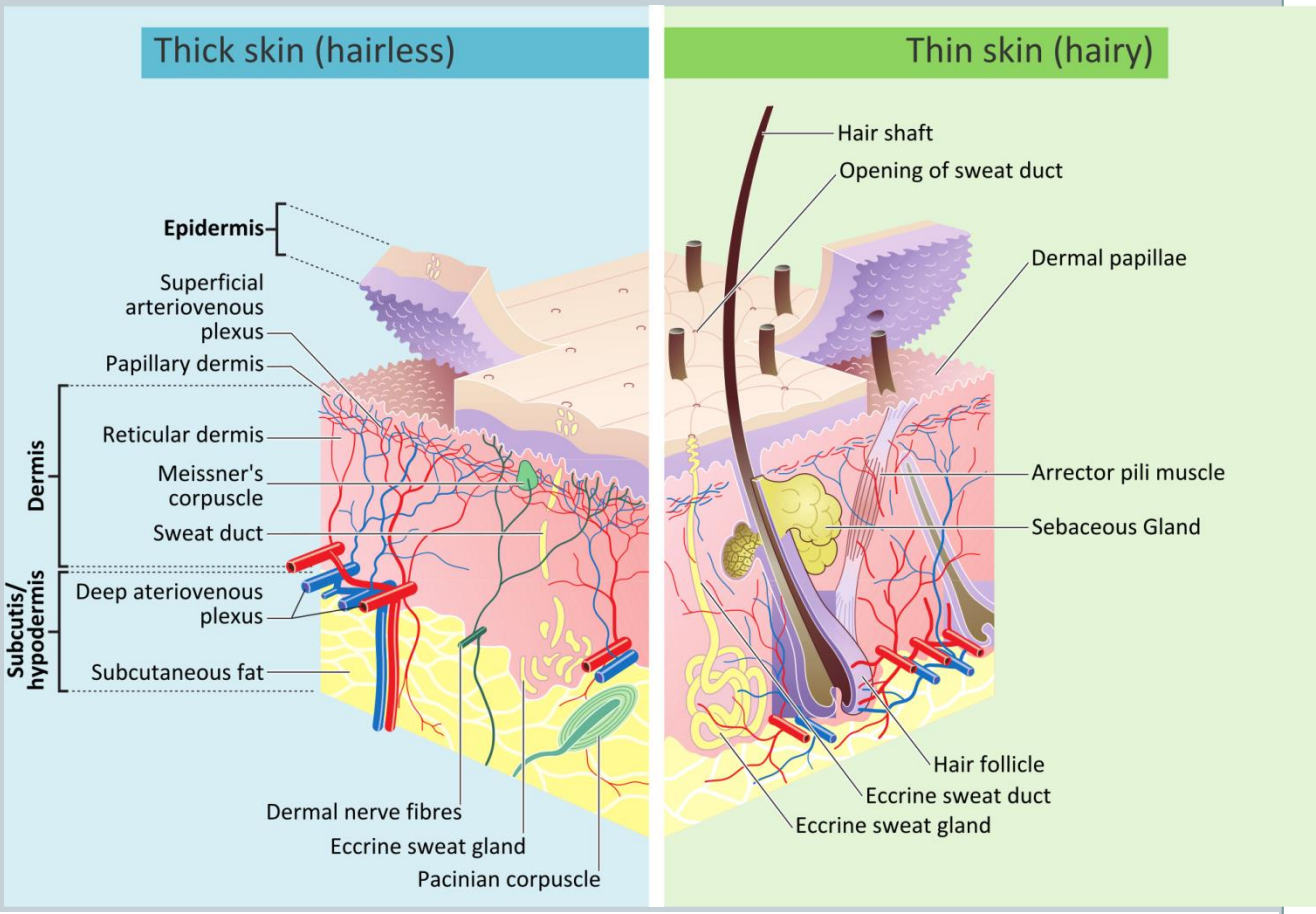
Assorbimento cutaneo

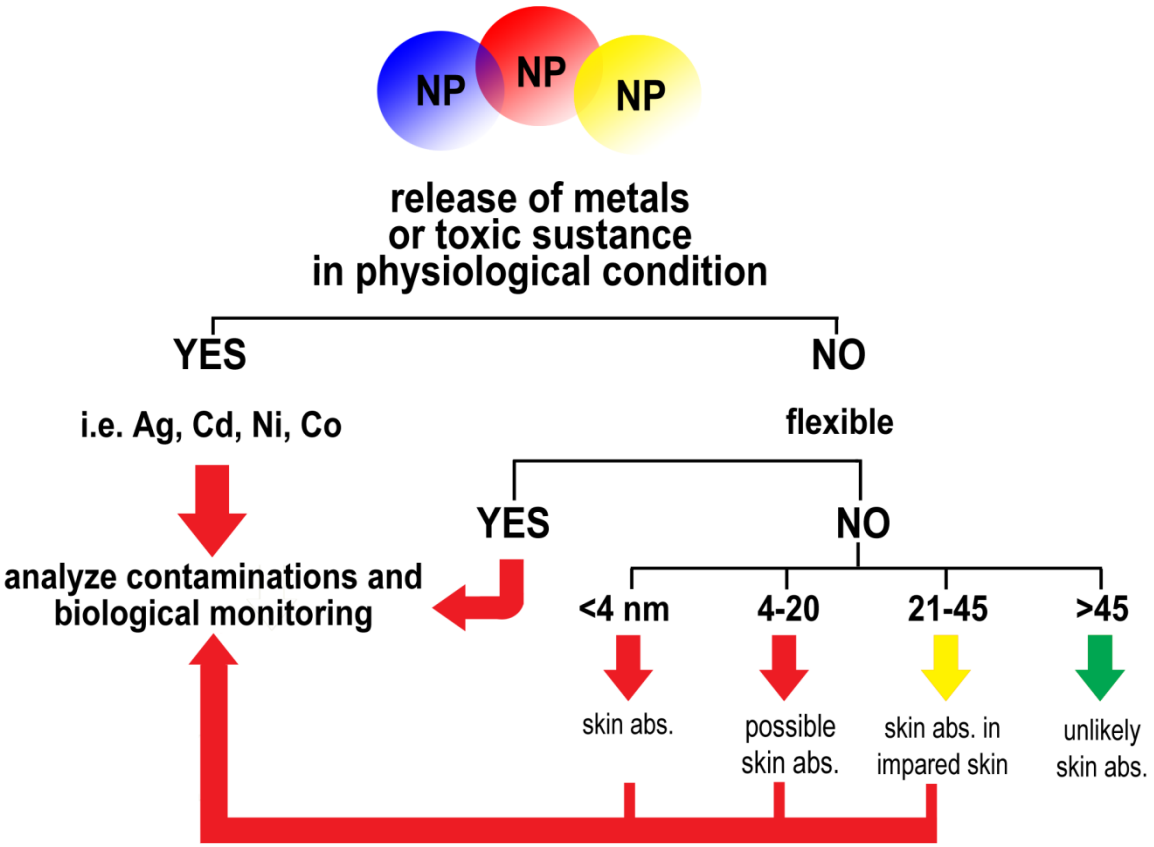
- Effetti locali
- Effetti sistemici

- s



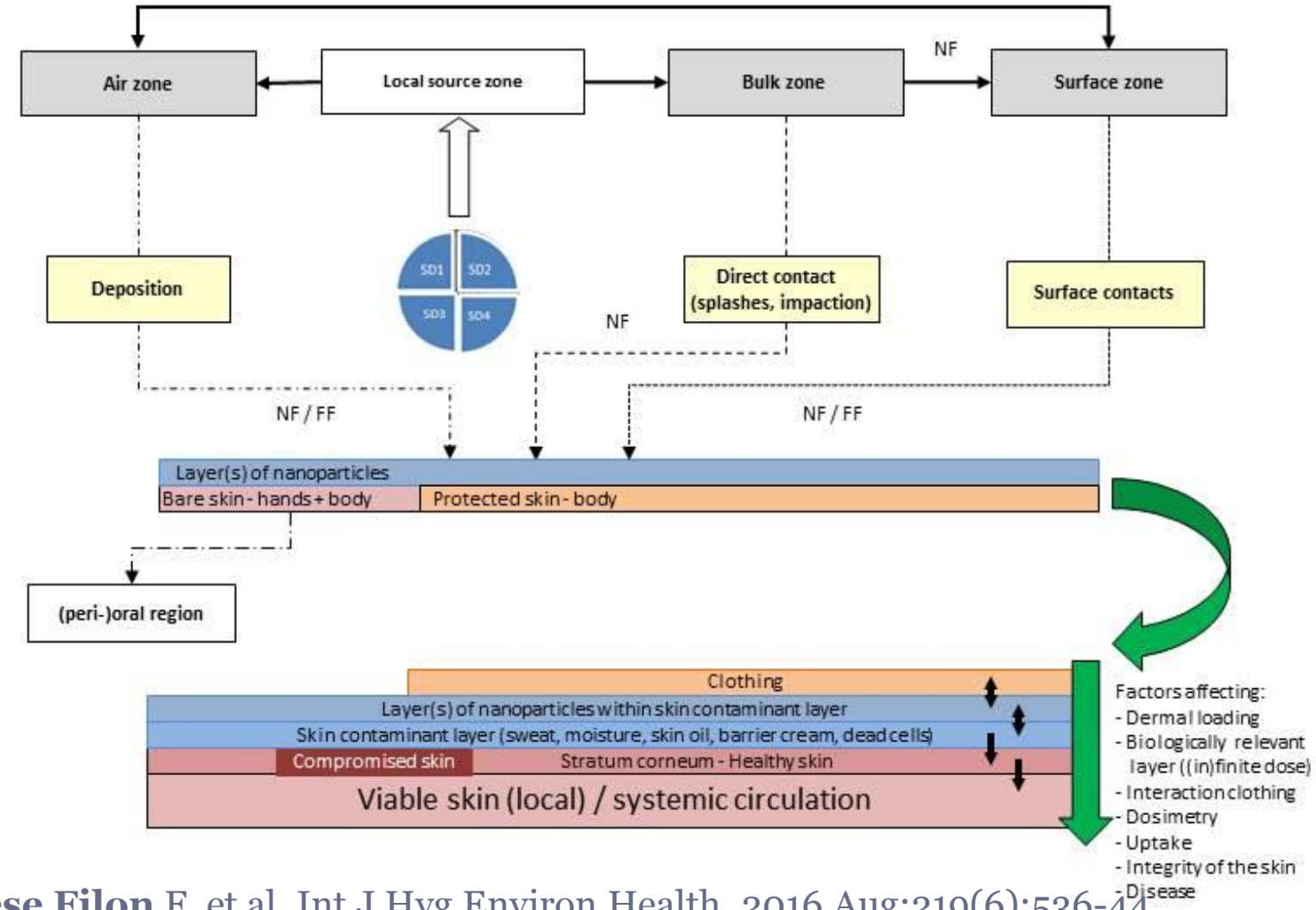
Assorbimento cutaneo

- Assorbimento delle nanoparticelle e storage nei follicoli piliferi
- Ti02 aumento ROS dopo esposizione solare ?
- Effetti allergizzanti per NP che contengono metalli sensibilizzanti (Co, Ni, Pd, ecc.)
- Penetrazione e diffusione nel corpo di NP



Evitare il contatto cutaneo

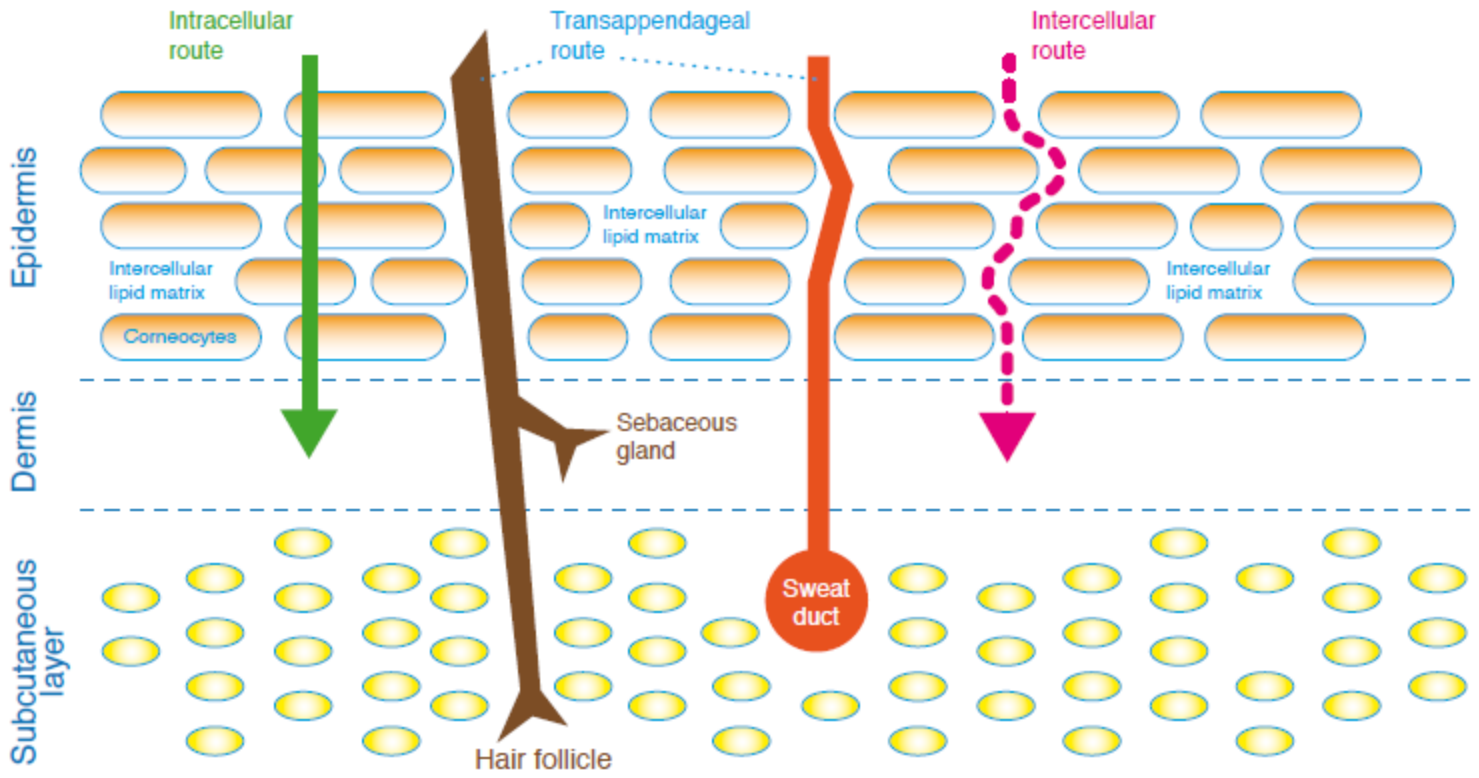
Conceptual framework for dermal exposure to nanoparticles (and relevance for ingestion exposure)



Larese Filon F, et al. Int J Hyg Environ Health. 2016 Aug;219(6):536-44.

Brouwer DH, et al. Int J Hyg Environ Health. 2016 Aug;219(6):503-12.

Skin absorption pathways



Penetration: NPs inside the skin
Permeation: throught the skin

Crosera M, Larese F. 2012
(Scheuplein 1965, 1967, Lademann 2009)

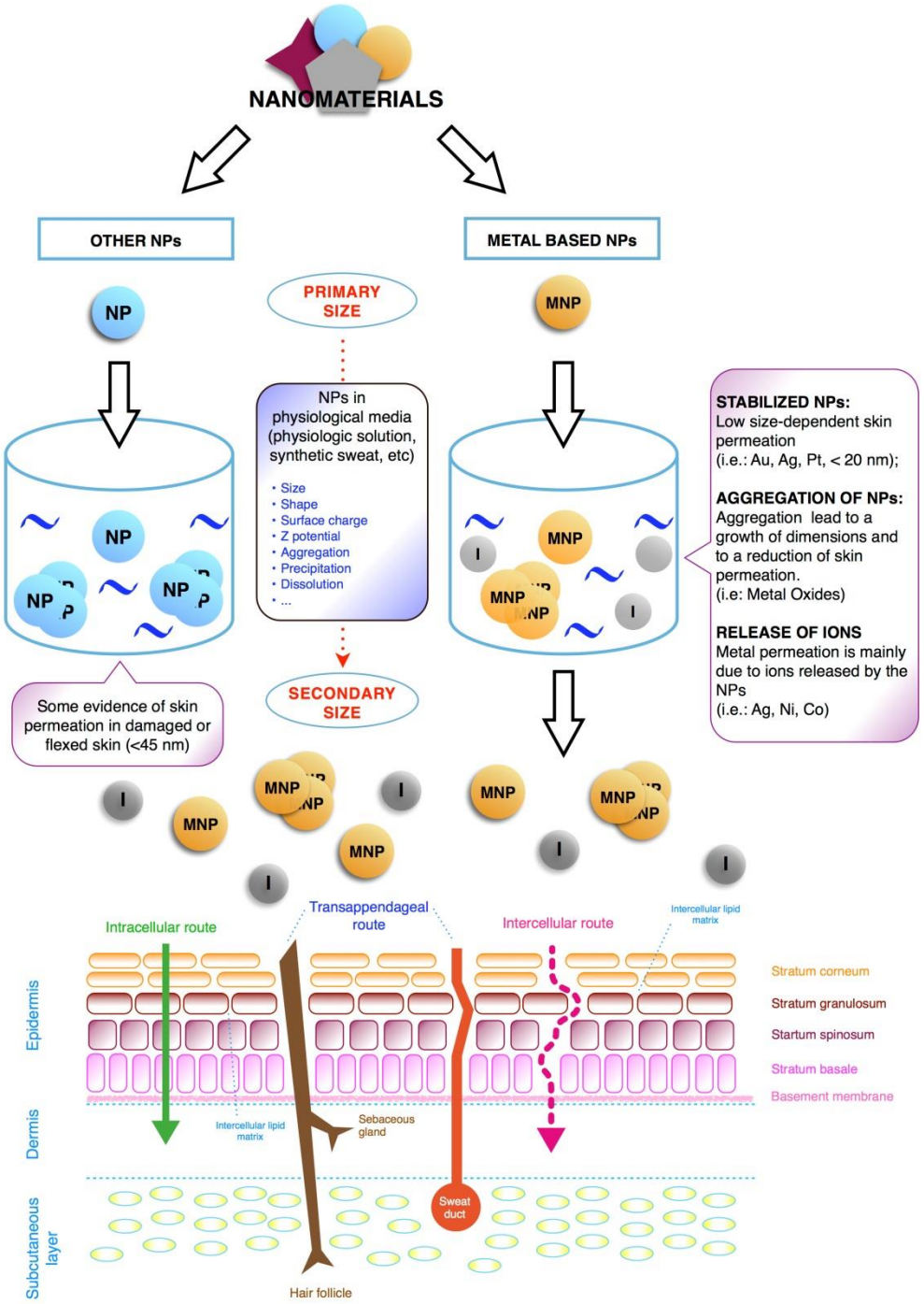
FACTORS INVOLVED

- Skin factors (2 m^2)
  - Contaminated area
  - Time of contamination
  - Cleaning procedures
  - Stratum corneum turnover
  - Skin conditions (atopic skin, barrier conditions)
  - Annexes
  - Protective equipment
  - gloves

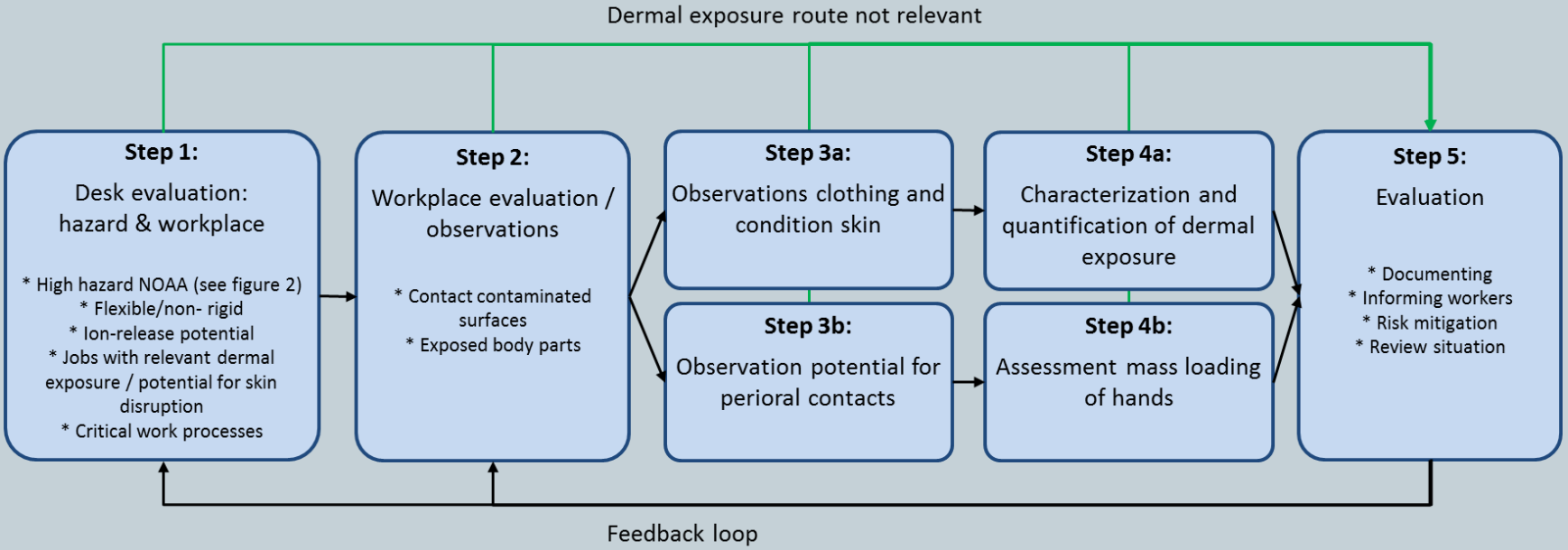
Example of 'flagged' job titles with high incidence of occupational skin diseases and potential for dermal exposure to nanomaterials / nanoproducts

Sector	Job title	Example of nanomaterials/ products
Health Care	Dental practitioner/ assistant/ technician	Nanocomposites
	Nurses	Nanomedicine
Personal care	Hairdresser	Variety of personal care products
	Beauticians/ visagists	
Construction	Construction painters	Coatings, paints
	Concrete repair workers	Mortars
Cleaning	Cleaners	Cleaning and dirt repellent coatings
Automotive	Car (body) repair workers	Primers, paints, nanocomposites

Brouwer DH, Spaan S, Roff M, Sleeuwenhoek A, Tuinman I, Goede H, van Duuren-Stuurman B,**Filon** FL, Bello D, Cherrie JW. Int J Hyg Environ Health. 2016 Aug;219(6):503-12


NANOMATERIALS
OTHER NPs
METAL BASED NPs
NP
MNP
PRIMARY SIZE
NPs in physiological media (physiologic solution, synthetic sweat, etc)
• Size
• Shape
• Surface charge
• Z potential
• Aggregation
• Precipitation
• Dissolution
• ...
STABILIZED NPs:
Low size-dependent skin permeation
(i.e.: Au, Ag, Pt, < 20 nm);
AGGREGATION OF NPs:
Aggregation lead to a growth of dimensions and to a reduction of skin permeation.
(i.e: Metal Oxides)
RELEASE OF IONS
Metal permeation is mainly due to ions released by the NPs
(i.e.: Ag, Ni, Co)
Some evidence of skin permeation in damaged or flexed skin (<45 nm)
SECONDARY SIZE
I
Intracellular route
Transappendageal route
Intercellular route
Intercellular lipid matrix
Epidermis
Dermis
Subcutaneous layer
Stratum corneum
Stratum granulosum
Startum spinosum
Stratum basale
Basement membrane
Sebaceous gland
Sweat duct
Hair follicle

A proposal for risk assessment 1



In figure 1 an overview of this stepwise approach is given. After each step a conclusion shall be made whether the situation at the workplace is considered to be safe based on the information that is gathered during that part of the assessment. If the situation is not considered to be safe, one shall proceed to the following step of the assessment.

A proposal for risk assessment 2

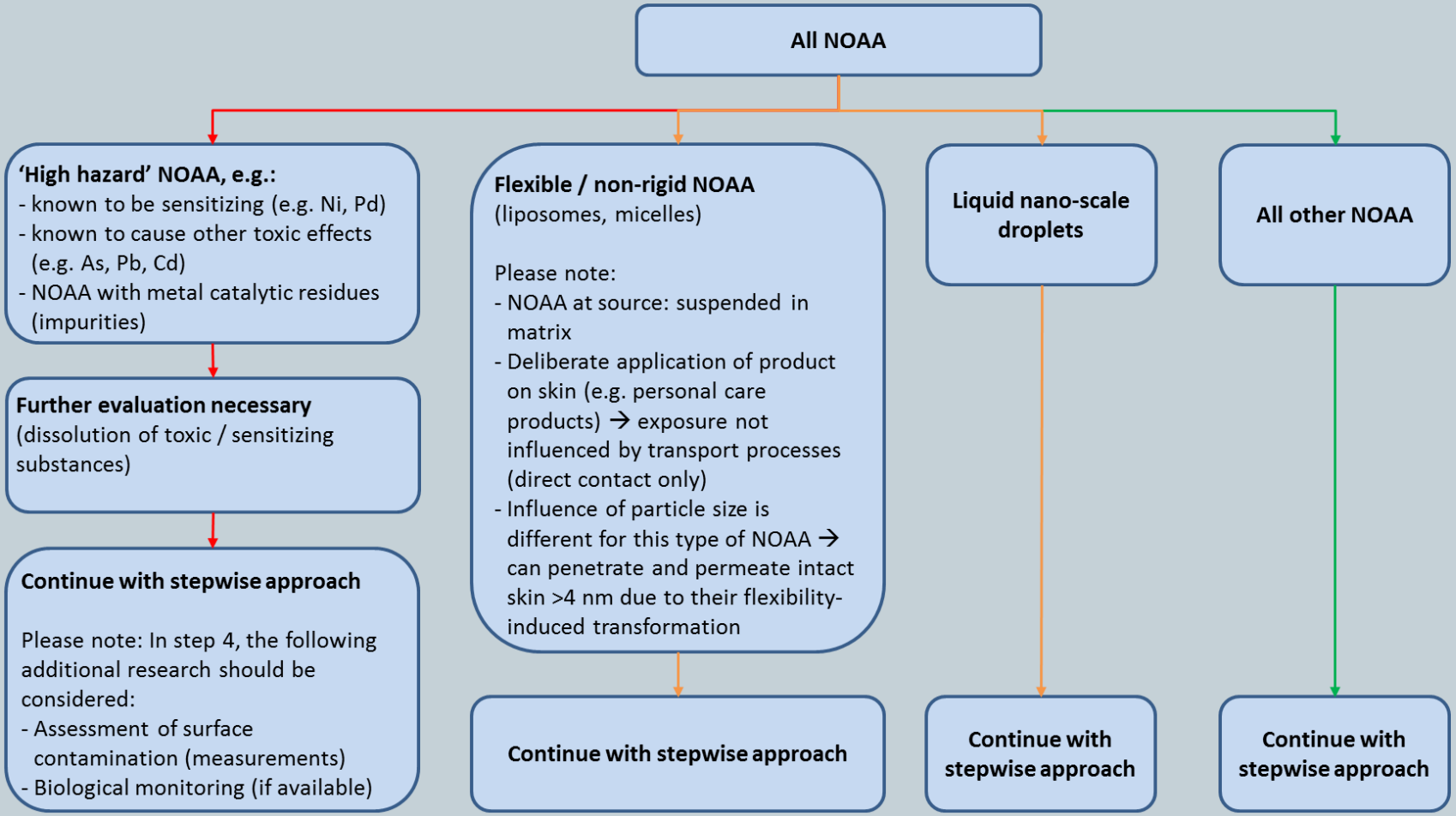
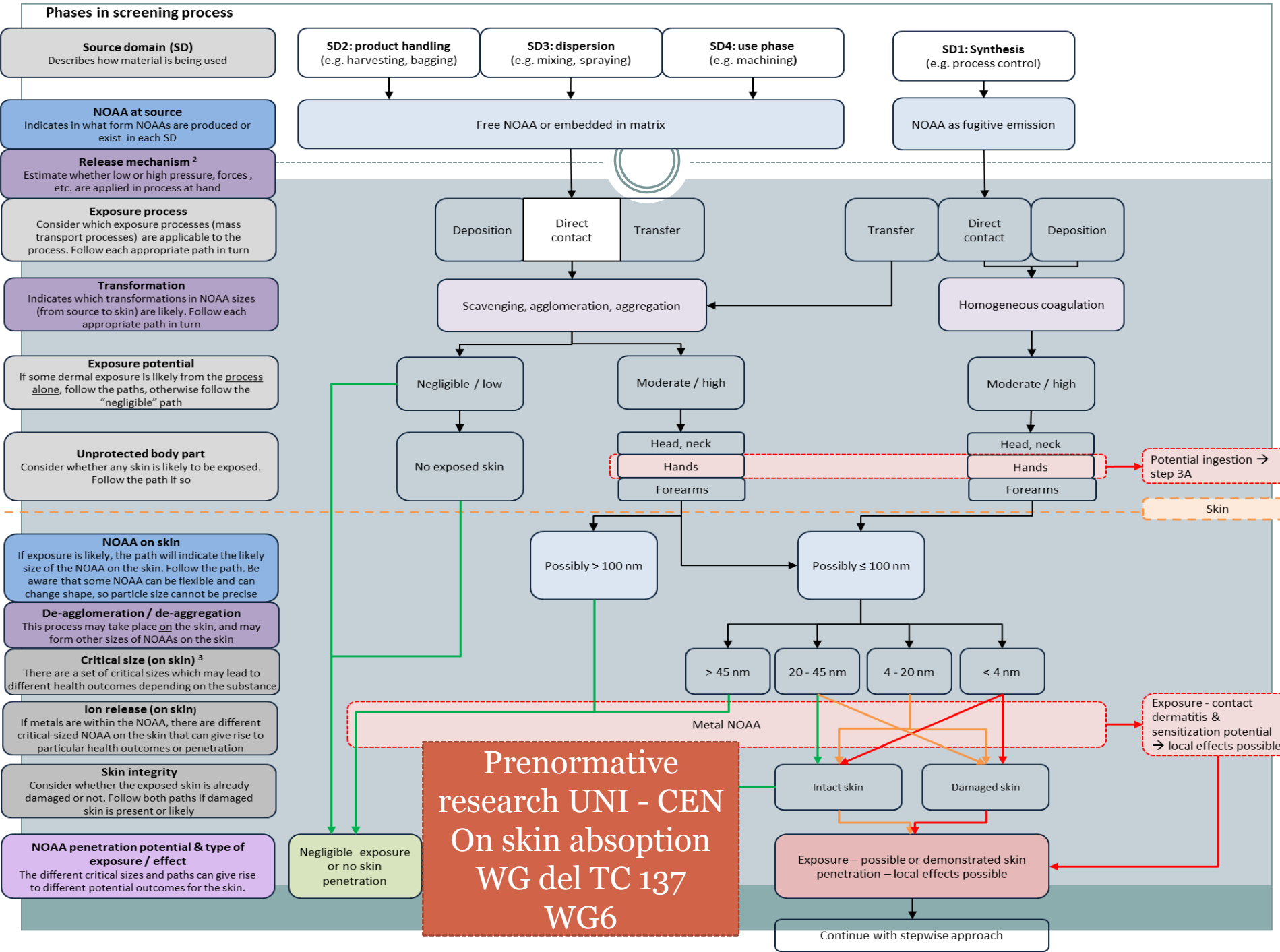
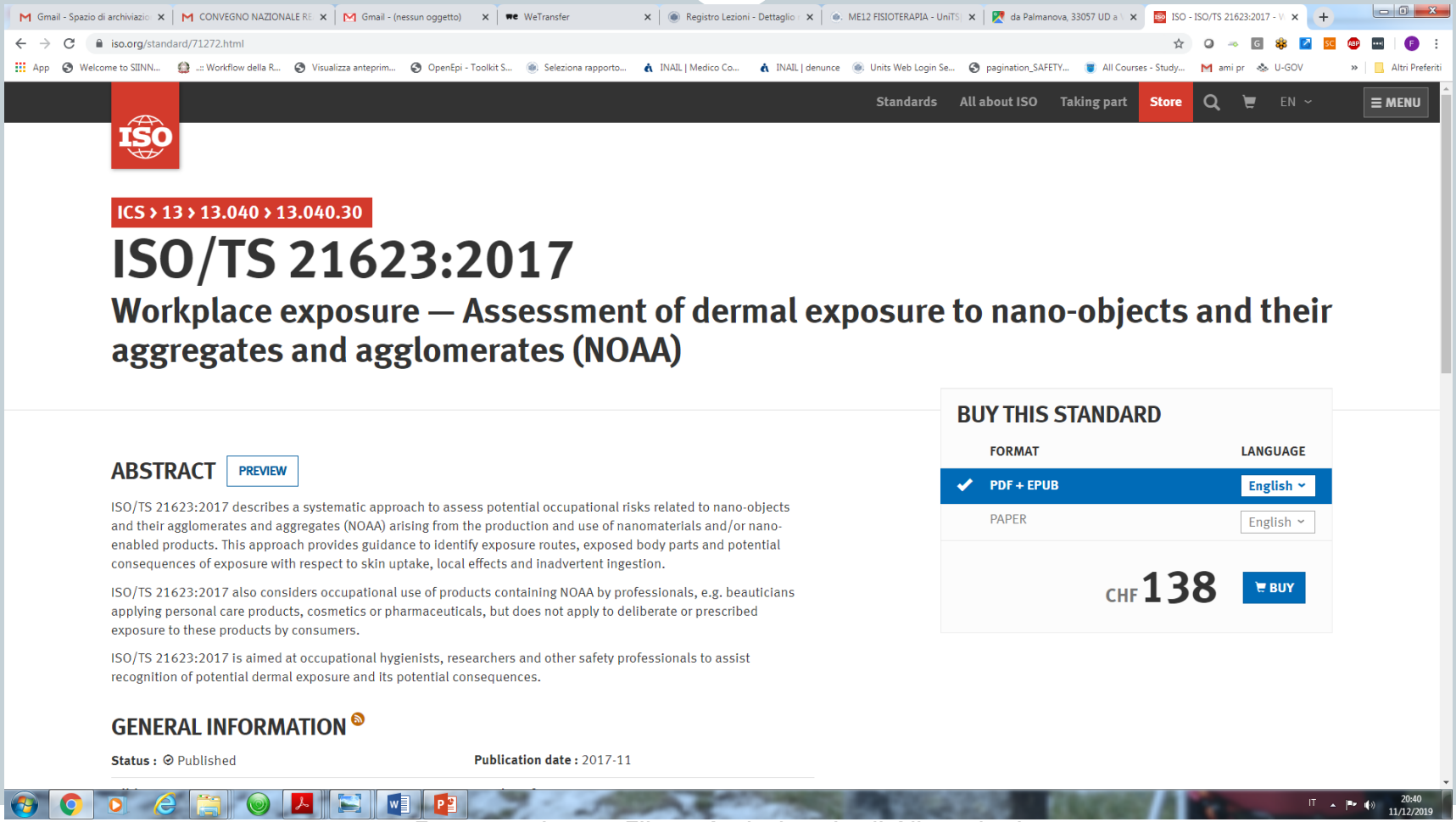


Figure 2 — Schematic overview of primary evaluation based on composition of NOAA and following steps (CEN document)


Phases in screening process
Source domain (SD)
Describes how material is being used
SD2: product handling
(e.g. harvesting, bagging)
SD3: dispersion
(e.g. mixing, spraying)
SD4: use phase
(e.g. machining)
SD1: Synthesis
(e.g. process control)
NOAA at source
Indicates in what form NOAAs are produced or exist in each SD
Free NOAA or embedded in matrix
NOAA as fugitive emission
Release mechanism [2]
Estimate whether low or high pressure, forces , etc. are applied in process at hand
Exposure process
Consider which exposure processes (mass transport processes) are applicable to the process. Follow each appropriate path in turn
Deposition
Direct contact
Transfer
Transfer
Direct contact
Deposition
Transformation
Indicates which transformations in NOAA sizes (from source to skin) are likely. Follow each appropriate path in turn
Scavenging, agglomeration, aggregation
Homogeneous coagulation
Exposure potential
If some dermal exposure is likely from the process alone, follow the paths, otherwise follow the "negligible" path
Negligible / low
Moderate / high
Moderate / high
Unprotected body part
Consider whether any skin is likely to be exposed. Follow the path if so
No exposed skin
Head, neck
Hands
Forearms
Head, neck
Hands
Forearms
Potential ingestion → step 3A
Skin
NOAA on skin
If exposure is likely, the path will indicate the likely size of the NOAA on the skin. Follow the path. Be aware that some NOAA can be flexible and can change shape, so particle size cannot be precise
Possibly > 100 nm
Possibly ≤ 100 nm
De-agglomeration / de-aggregation
This process may take place on the skin, and may form other sizes of NOAAs on the skin
Critical size (on skin) [3]
There are a set of critical sizes which may lead to different health outcomes depending on the substance
> 45 nm
20 - 45 nm
4 - 20 nm
< 4 nm
Ion release (on skin)
If metals are within the NOAA, there are different critical-sized NOAA on the skin that can give rise to particular health outcomes or penetration
Metal NOAA
Exposure - contact dermatitis & sensitization potential → local effects possible
Skin integrity
Consider whether the exposed skin is already damaged or not. Follow both paths if damaged skin is present or likely
Intact skin
Damaged skin
NOAA penetration potential & type of exposure / effect
The different critical sizes and paths can give rise to different potential outcomes for the skin.
Negligible exposure or no skin penetration
Exposure – possible or demonstrated skin penetration – local effects possible
Continue with stepwise approach
Prenormative research UNI - CEN
On skin absoption
WG del TC 137
WG6


iso.org/standard/71272.html
Standards
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ICS › 13 › 13.040 › 13.040.30
ISO/TS 21623:2017
Workplace exposure — Assessment of dermal exposure to nano-objects and their aggregates and agglomerates (NOAA)
BUY THIS STANDARD
FORMAT
LANGUAGE
PDF + EPUB
English
PAPER
English
CHF 138
BUY
ABSTRACT
PREVIEW
ISO/TS 21623:2017 describes a systematic approach to assess potential occupational risks related to nano-objects and their agglomerates and aggregates (NOAA) arising from the production and use of nanomaterials and/or nano-enabled products. This approach provides guidance to identify exposure routes, exposed body parts and potential consequences of exposure with respect to skin uptake, local effects and inadvertent ingestion.
ISO/TS 21623:2017 also considers occupational use of products containing NOAA by professionals, e.g. beauticians applying personal care products, cosmetics or pharmaceuticals, but does not apply to deliberate or prescribed exposure to these products by consumers.
ISO/TS 21623:2017 is aimed at occupational hygienists, researchers and other safety professionals to assist recognition of potential dermal exposure and its potential consequences.
GENERAL INFORMATION
Status : Published
Publication date : 2017-11

NORMA EUROPEA

Esposizione nei luoghi di lavoro - Misura dell'esposizione per inalazione dei nanomateriali e dei loro aggregati e agglomerati (NOAA) - Parametri da usare come concentrazione del numero di particelle, concentrazione dell'area superficiale e concentrazione della massa

UNI EN 16966

GENNAIO 2019

UNICHIM
UNIstore - Download prepagato - download del 13/02/2019

NORMA EUROPEA

Esposizione nei luoghi di lavoro - Valutazione dell'esposizione per inalazione dei nanomateriali e dei loro aggregati o agglomerati

UNI EN 17058

GENNAIO 2019

Workplace exposure - Assessment of exposure by inhalation of nano-objects and their aggregates and agglomerates

Scand J Work Environ Health. 2019 May 1;45(3):217-238. doi: 10.5271/sjweh.3800. Epub 2019 Jan 17.

Current state of knowledge on the health effects of engineered nanomaterials in workers: a systematic review of human studies and epidemiological investigations.

- Schulte PA[1], Leso V, Niang M, Iavicoli I.

- The review found **limited evidence** of adverse effects in workers exposed to the most commonly used ENM.
- However, some biological alterations are suggestive for possible adverse impacts.
- The primary targets of some ENM exposures were the **respiratory and cardiovascular systems**.
-

- There is a need for longitudinal epidemiologic investigations with clear exposure characterizations for various ENM to discover potential adverse health effects and identify possible indicators of early biological alterations.
- In this state of uncertainty, **precautionary controls** for each ENM are warranted while further study of potential health effects continues.

Conclusioni

- Abbiamo ancora pochi dati sui lavoratori esposti
- E' necessario **evitare l'esposizione per via inalatoria** ai nanomateriali usando formulazioni umide, sistemi chiusi, glove-box, aspirazione localizzata, dispositive di protezione individuale

I dati evidenziamo maggior rischio
per
Patologie polmonari
Tumore polmonare

Evitare la traslocazione

Conclusioni - 2

- E' necessario **evitare il contatto cutaneo** (usare doppi guanti protettivi in nitrile)

I dati evidenziamo maggior rischio per
Allergie cutanee (se metalli allergenici)
Assorbimento sistemico

Worker exposure

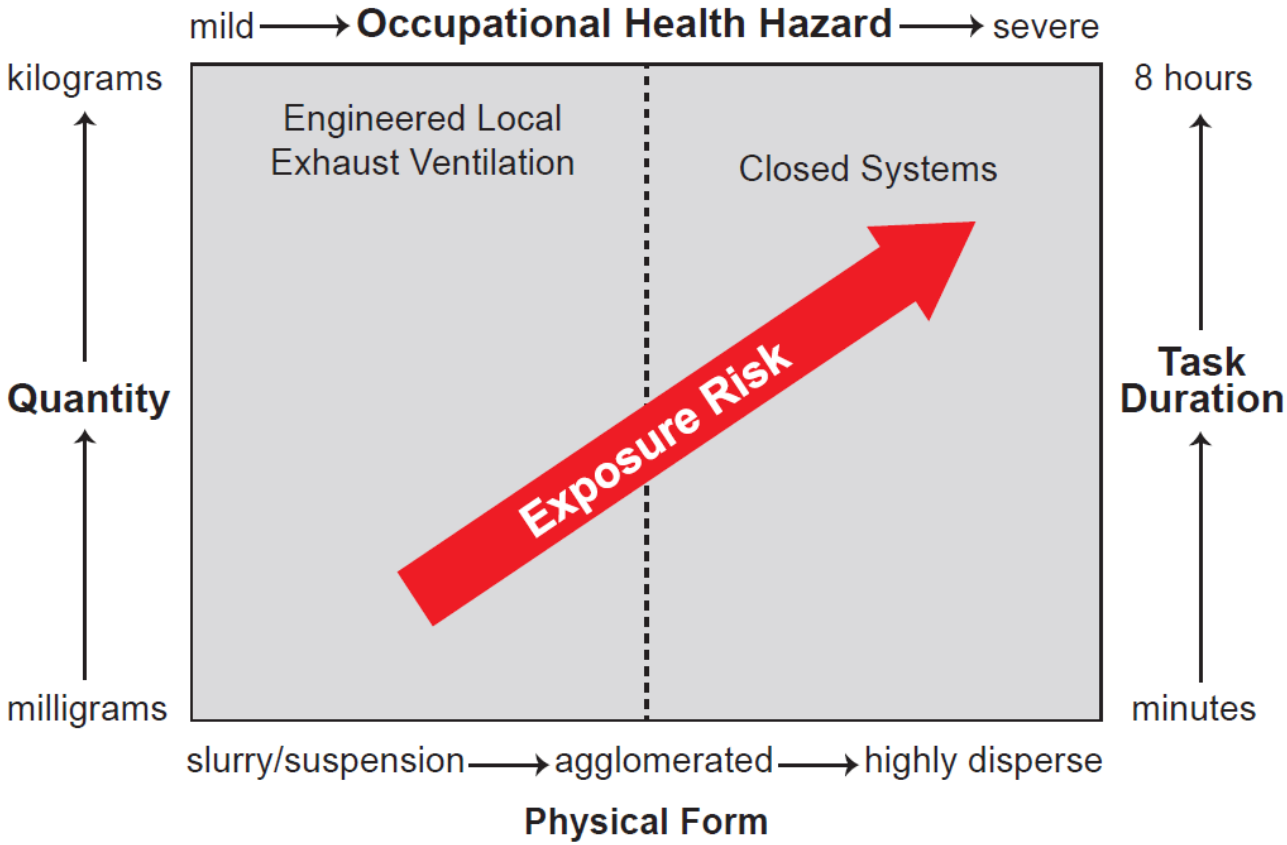

Figure 6. Factors influencing control selection [NIOSH 2009a].

Worker exposure

Figure 10. Nanomaterial worker wearing personal protective equipment in a work area with local engineering controls. Photo by Mark Methner, NIOSH.

Grazie dell'attenzione!

Conclusioni

- Evitare l'esposizione per via inalatoria
- Evitare il contatto cutaneo

Formulazioni umide
Glove box
Aspirazione localizzata
Mezzi di protezione

Doppio guanto protettivo
Camici in tyvek