

What is common between sweets, buildings and sunscreens? *On the risk assessment and regulation of chemicals in Europe*

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TiO_2 - Titania



Physical properties of TiO_2

- White inorganic compound
- Occurs naturally as a solid
- Insoluble in water, even in its particle form
- Extremely high melting point of $1,843^\circ\text{C}$ and boiling point of $2,972^\circ\text{C}$
- Refractive index (ability to scatter UV light) very high >>> diamond
- Photocatalytic activity under UV light



=> Resistant, extra-white, bright, protective, aesthetic, very promising

<https://tdma.info/uses-of-titanium-dioxide/>

<https://www.youtube.com/watch?v=7ObnoGtDi0Q&t=93s/>

What is titanium dioxide?



- White inorganic compound
- As a white pigment, TiO_2 is one of the most important raw materials for paints and coatings
- As a [photocatalyst](#), titanium dioxide can be added to paints, cements, windows and tiles in order to [decompose environmental pollutants](#).
- Beyond paints, catalytic coatings, plastics, paper, pharmaceuticals and sunscreen, some [lesser-known applications include packaging, commercial printing inks, cosmetics, toothpastes, and food](#) ([E171](#))

What do we know regarding TiO₂ safety ?

 [Tous](#)  [Images](#)  [Vidéos](#)  [Actualités](#)  [Maps](#)  [Plus](#) [Paramètres](#) [Outils](#)

Environ 8 110 000 résultats (0,73 secondes)

Titanium dioxide (TiO₂) is considered as an inert and **safe** material and has been used in many applications **for** decades. ... Although TiO₂ is permitted as an additive (E171) in food and pharmaceutical products **we do** not have reliable data **on** its absorption, distribution, excretion and toxicity **on** oral exposure.

<https://www.ncbi.nlm.nih.gov/articles/PMC3423755>

Titanium dioxide in our everyday life; is it safe? - NCBI - NIH

Conclusions

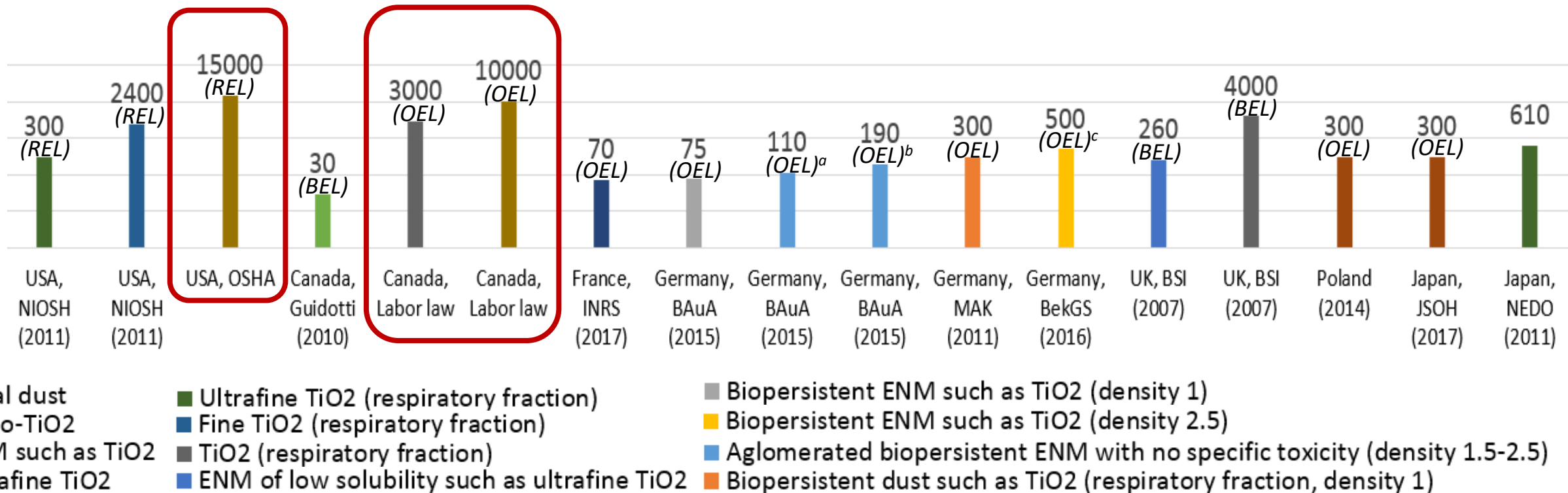
Until relevant toxicological and human exposure data that would enable reliable risk assessment are obtained, TiO₂ nanoparticles should be used with great care.

[Radiol Oncol.](#) 2011 Dec; 45(4): 227–247.

Published online 2011 Nov 16. doi: [10.2478/v10019-011-0037-0](https://doi.org/10.2478/v10019-011-0037-0)

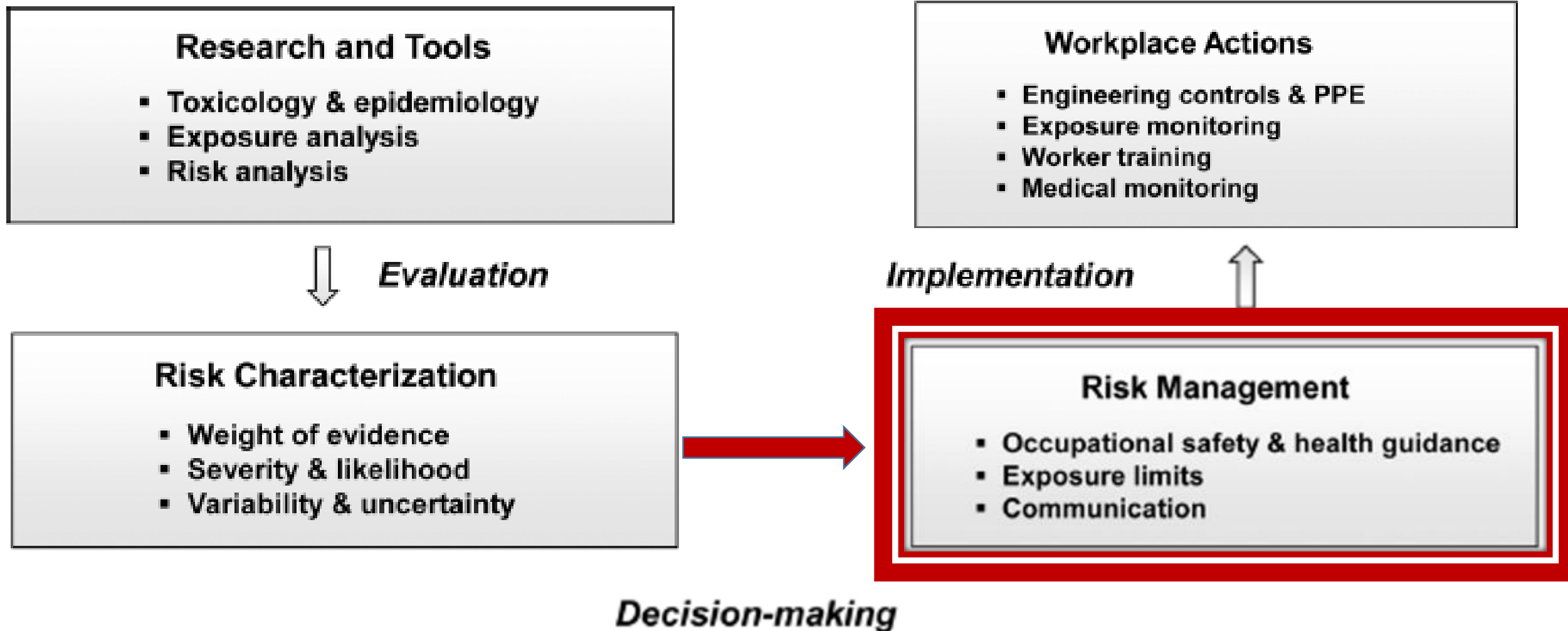
What do we know regarding TiO₂ safety ?

- Currently available Occupational Exposure Limits (OEL) in µg/m³

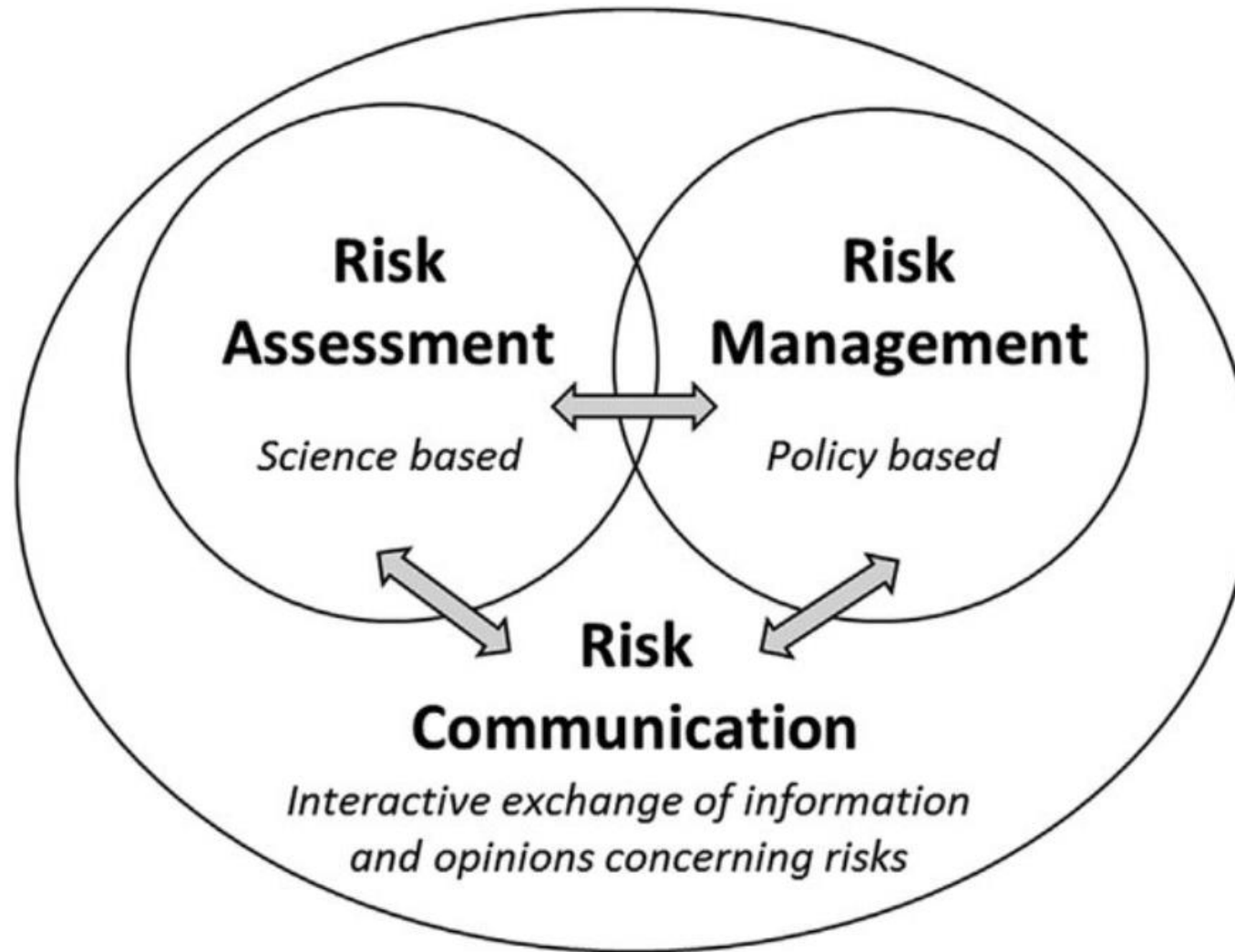


Abbreviations: REL, recommended exposure limit; PEL, permissible exposure limit; BEL, benchmark exposure level; OEL^a, OEL for cancer risk 1/5000; OEL^b, OEL for cancer risk 1/2000 ; OEL^c, regulatory OEL, OEL PL^d, 15y period limited OEL; ENM, engineered nanomaterials

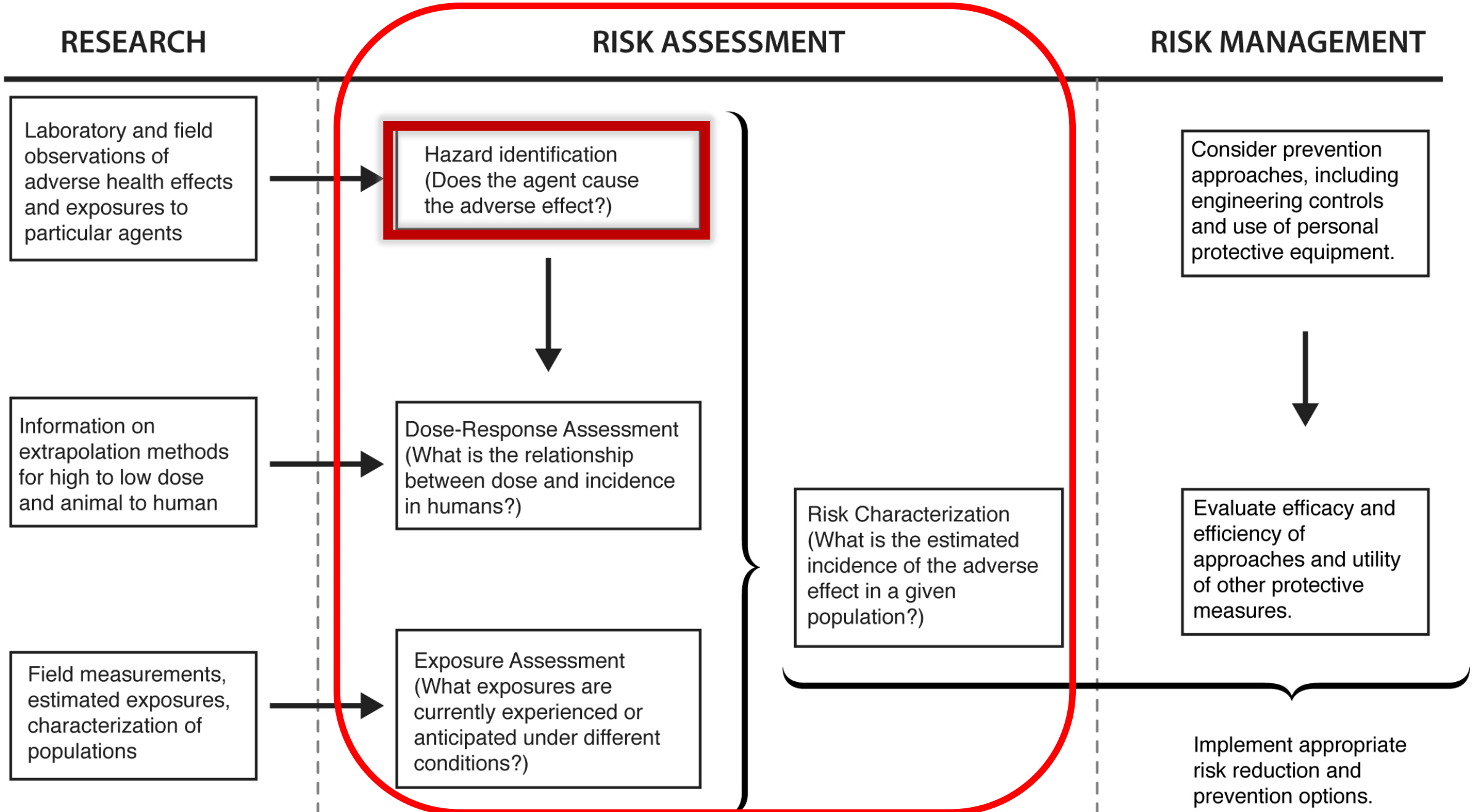
NIOSH framework of Risk Assessment & Risk Management



WHO risk analysis framework



US NRC Risk Assessment/Risk Management framework



Hazard identification

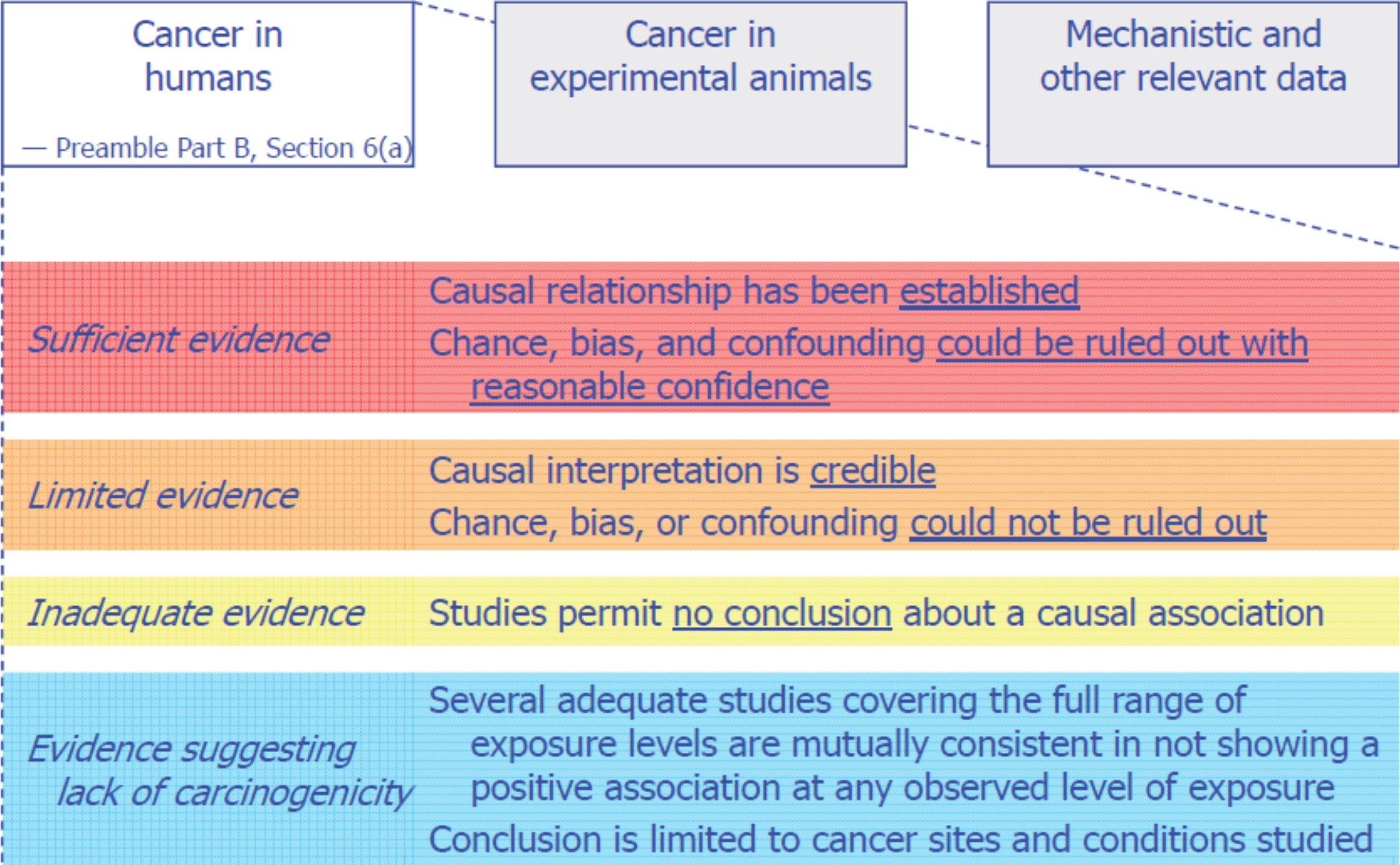
- **Slowly soluble particles not otherwise regulated or classified** (TWA of total suspended particles or dusts)
- **Case report Yamadori *et al.* (1986)** reported a papillary adenocarcinoma of the lung and titanium dioxide-associated pneumoconiosis in a male titanium dioxide packer with 13 years of potential dust exposure and a 40-year history of tobacco smoking.
- **1st assessment IARC Monographs** on the Evaluation of Carcinogenic Risks to Humans Volume 47 (**IARC, 1989**) => Not classifiable as to its carcinogenicity to humans (**group 3**)

IARC
Classification
framework

		EVIDENCE IN EXPERIMENTAL ANIMALS			
		<i>Sufficient</i>	<i>Limited</i>	<i>Inadequate</i>	<i>ESLC</i>
EVIDENCE IN HUMANS	<i>Sufficient</i>	Group 1 (<i>carcinogenic to humans</i>)			
	<i>Limited</i>	Group 2A (<i>probably carcinogenic</i>)	Group 2B (<i>possibly carcinogenic</i>) (exceptionally, Group 2A)		
	<i>Inadequate</i>	Group 2B (<i>possibly carcinogenic</i>)	Group 3 (<i>not classifiable</i>)		
	<i>ESLC</i>				Group 4

ESLC: Evidence suggesting lack of carcinogenicity

IARC
evaluation
Framework for
human data



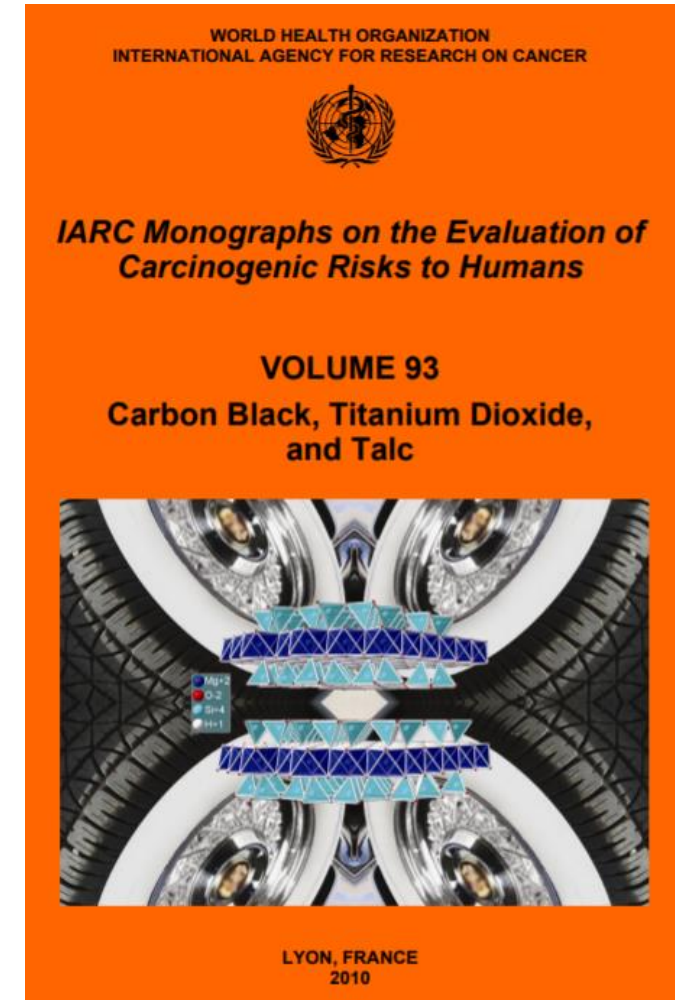
Hazard identification

- 2nd assessment in 2006 Volume 93 (IARC, 2010) => Possibly carcinogenic to humans (**Group 2B**)
 - There is *inadequate evidence* in humans for the carcinogenicity of titanium dioxide.
 - There is *sufficient evidence* in experimental animals for the carcinogenicity of titanium dioxide

Human carcinogenicity data

- Chen & Fayerweather (1988); Fayerweather *et al.* (1992), USA
- Fryzek *et al.* (2003), USA
- Boffetta *et al.* (2004), 6 EU countries

«**All the studies had methodological limitations.** ...None of the studies was designed to assess the impact of particle size (fine or ultrafine) or the potential effect of the coating compounds on the risk for lung cancer.»



And what happened since ?



In the USA, *NIOSH Current Intelligence Bulletin (April 2011)*

- Quantitative risk assessments for fine and ultrafine TiO₂
 - **Hazard identification** in humans

Lung cancer mortality

Europe SMR (95% CI) *Boffetta et al (2001)*

Males 1.23
(1.10-1.38)

Females 0.8
(0.02-4.09)

Finland

0.76
(0.39-1.32)

France

1.42
(0.99-1.96)

Germany

1.51
(1.26-1.79)

Italy

0.97
(0.50-1.69)

Norway

0.79
(0.21-2.02)

UK

1.09
(0.90-1.31)

Amérique du nord

US SMR (95% CI)

*Fryzek et al
(2003)*

1.00 (0.80-1.30)

*Chen &
Frayerweather
(2003)*

0.52 (??-??)

*Ellis et al
(2010)*

0.90 (0.75-1.05)
1.02 (0.84-1.22)

*Ellis et al
(2013)*

0.98 (0.78-1.21)
1.35 (1.07-1.66)^(a)
{ **1.15 (0.94-1.39)**
1.68 (1.32-2.11)^(a)}

Canada OR (95% CI)

*Boffetta et al (2001)
Ramanakumar et al (2008)*

Study I

1.1 (0.7-2.0)^(a)
1.2 (0.8-1.09)^(b)

Study II

M 1.0 (0.7-2.1)
F 0.5 (0.1-3.4)

Pooled

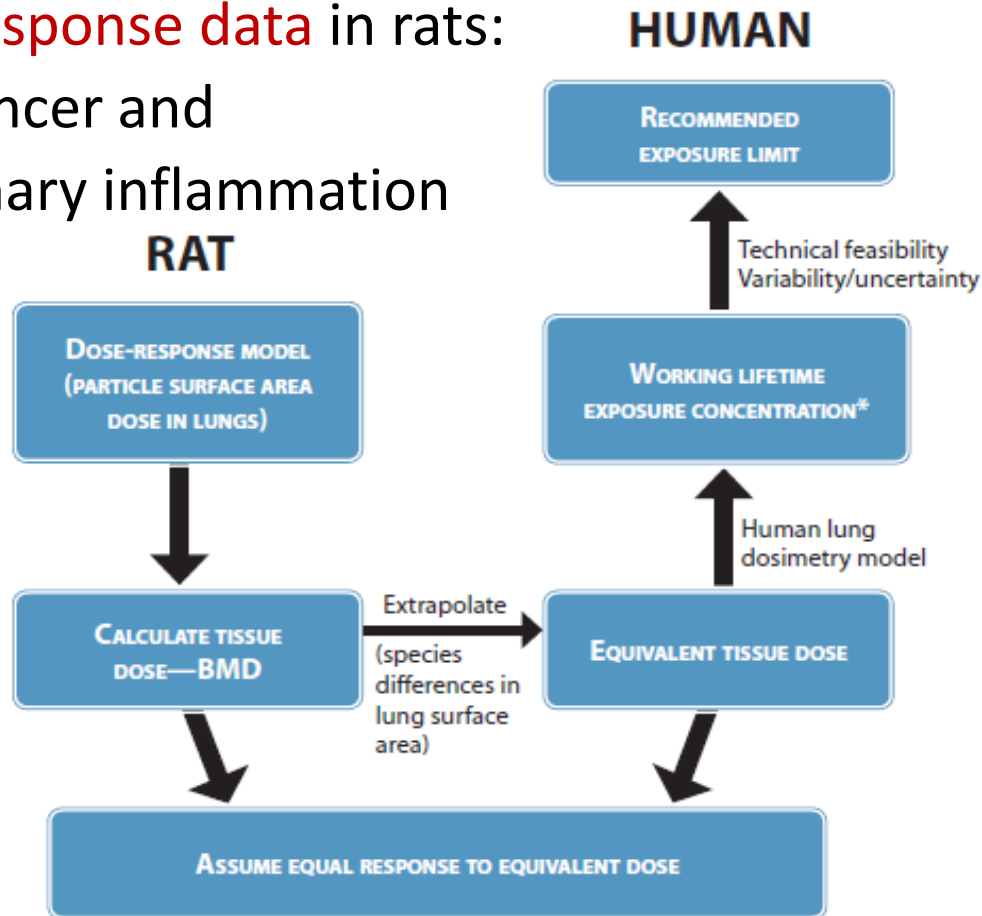
1.0 (0.8-1.5)^(c)

And what happened since ?

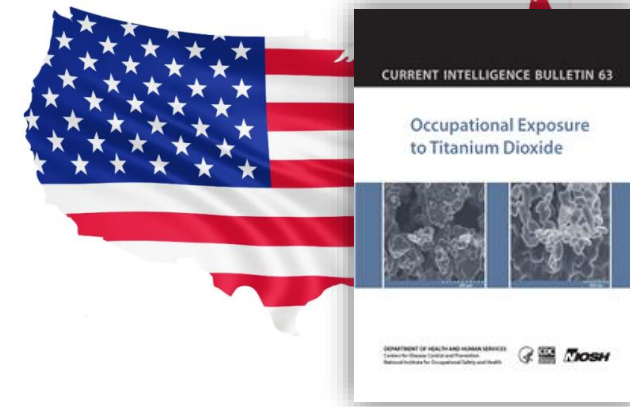
In the USA, *NIOSH Current Intelligence Bulletin (April 2011)*

- Quantitative risk assessments

- **Dose-response data** in rats:
lung cancer and
pulmonary inflammation



*Compare rat-based risk estimates with upper bound on risk from human studies



NIOSH recommends exposure limits of 2.4 mg/m³ for fine TiO₂ and 0.3 mg/m³ for ultrafine (including engineered nanoscale) TiO₂, as time-weighted average (TWA) concentrations for up to 10 hours per day during a 40-hour work week. NIOSH has determined that ultrafine TiO₂ is a potential occupational carcinogen but that there are insufficient data at this time to classify fine TiO₂ as a potential occupational carcinogen. However, as a precautionary step, NIOSH used all of the animal tumor response data when conducting dose-response modeling and determining separate RELs for ultrafine and fine TiO₂. These recommendations represent levels that over a working lifetime are estimated to reduce risks of lung cancer to below 1 in 1,000. NIOSH realizes that knowledge about the health effects of nanomaterials is an evolving area of science. Therefore, NIOSH intends to continue dialogue with the scientific community and will consider any comments about nano-size titanium dioxide for future updates of this document. (Send comments to nioshdocket@cdc.gov.)

NIOSH urges employers to disseminate this information to workers and customers and requests that professional and trade associations and labor organizations inform their members about the hazards of occupational exposure to respirable TiO₂.



And what happened since ?

In the EU

TiO₂ = poorly soluble,
low-toxicity particles



REACH Regulation aims to improve the protection of human health and the environment from the risks that can be posed by chemicals.



The **CLP** Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EU through classification and labelling of chemicals.

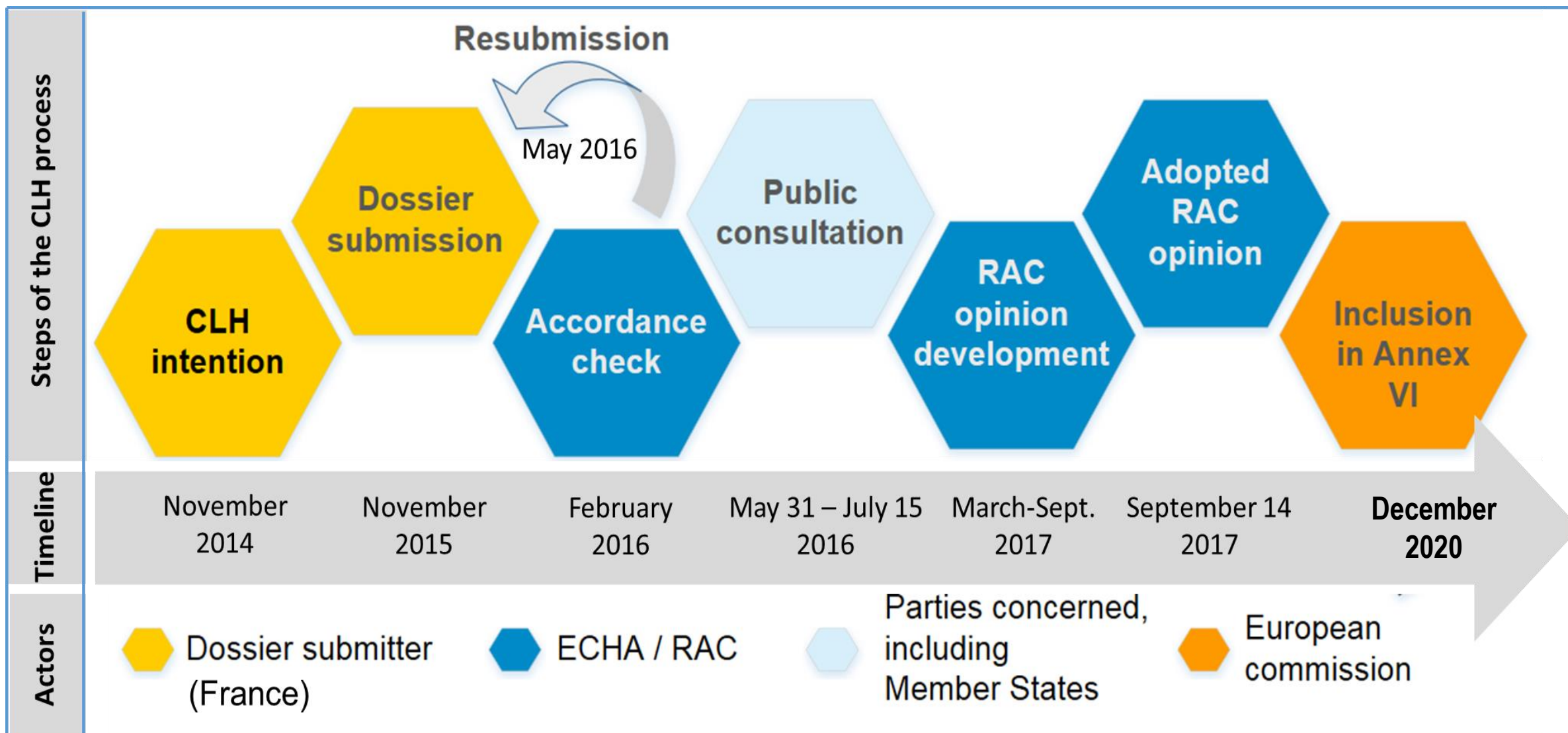


The **Chemical Agents Directive (CAD)** and the **Carcinogens and Mutagens Directive (CMD)** provide a framework for setting occupational exposure limits, forming an integral part of the EU's mechanism for protecting the health of workers.

EU CLP Regulation (*Classification, Labelling and Packaging of chemicals*)

- The identified hazards must be communicated to other actors in the supply chain, including consumers (via a label and a safety data sheet)
- The objective is to alert stakeholders to the presence of a danger and the need to manage the associated risks
- The CLP classification affects other EU laws such as the Workers Directive (CMD 2004/37 / EC), which sets binding OELs and BLVs
- Revision in the frame of the CLH procedure

CLH procedure for CLP regulation revision



Approach followed by France (ANSES) for TiO₂

- Systematic review of TiO₂ production worker cohorts
- Critical assessment of bias using the OHAT method and gradation of the level of evidence

USA: Chen & Fayerweather, 1988; Ellis *et al.*, 2010 & 2013; Fryzek *et al.*, 2003

Retrospective industry-based cohort mortality studies

*E.I. du Pont de Nemours
and Company plants*

1576 males
1935-1983

5054 & 3607 males
1935-2006

4241 workers
1960-2000

90% males
(n=3882)

2 plants

3 plants

4 plants

Europe: Boffetta *et al.*, 2004

Retrospective industry-based cohort mortality study

Finland

2270 workers
88% males

France

2346 workers
96% males

Germany

5019 workers
94% males

Italy

681 workers
99% males

Norway

436 workers
100% males

UK

4265 workers
100% males

→ 15017 workers

→ from (1950-1972) until (1997-2001)

→ 11 factories producing TiO₂

Initial corpus and Computerized
search of databases: 52 citations

Removing duplicates:
7 citations

Titles and abstracts read by
reviewers: 40 citations

Title and abstract not
related to the topic:
32 citations

Full articles retrieved and read:
7 citations

Case-control studies
in general population:
2 citations

Studies of TiO₂ workers included
for OHAT risk of bias
assessment: 5 citations

ANSES = The French Agency for Food, Environmental and Occupational Health & Safety

Mortality among workers employed in the titanium dioxide production industry in Europe*

Paolo Boffetta^{1,2,3}, Anne Soutar⁴, John W. Cherrie^{4,5}, Fredrik Granath², Aage Andersen⁶, Ahti Anttila⁷, Maria Blettner⁸, Valerie Gaborieau¹, Stefanie J. Klug⁸, Sverre Langard⁹, Daniele Luce¹⁰, Franco Merletti¹¹, Brian Miller⁴, Dario Mirabelli¹¹, Eero Pukkala⁷, Hans-Olov Adami¹ & Elisabete Weiderpass^{1,2,*}

Abstract

Objectives: To assess the risk of lung cancer mortality related to occupational exposure to titanium dioxide (TiO₂).

Methods: A mortality follow-up study of 15,017 workers (14,331 men) employed in 11 factories producing TiO₂ in Europe. Exposure to TiO₂ dust was reconstructed for each occupational title; exposure estimates were linked with the occupational history. Observed mortality was compared with national rates, and internal comparisons were based on multivariate Cox regression analysis.

Results: The cohort contributed 371,067 person-years of observation (3.3% were lost to follow-up and 0.7% emigrated). 2652 cohort members died during the follow-up, yielding standardized mortality ratios (SMRs) of 0.87 (95% confidence interval [CI] 0.83–0.90) among men and 0.58 (95% CI 0.40–0.82) among women. Among men, the SMR of lung cancer was significantly increased (1.23, 95% CI 1.10–1.38) however, mortality from lung cancer did not increase with duration of employment or estimated cumulative exposure to TiO₂ dust. Data on smoking were available for over one third of cohort members. In three countries, the prevalence of smokers was higher among cohort members compared to the national populations.

Conclusions: The results of the study do not suggest a carcinogenic effect of TiO₂ dust on the human lung.

Key words: titanium dioxide, mortality, lung cancer, occupation.

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Table 4. Standardized mortality ratios of selected causes by country

Cause of death		Country					
		Finland	France	Germany ^a	Italy	Norway	UK
All causes	Obs/Exp	224/276.1	305/313.8	1015/1131.7	89/99.8	84/96.0	902/1102.4
	SMR	0.81	0.97	0.90	0.89	0.87	0.82
	95% CI	0.71–0.92	0.87–1.09	0.84–0.95	0.72–1.10	0.70–1.08	0.77–0.87
All malignant neoplasms	Obs/Exp	34/51.2	125/103.3	319.5/298.3	28/37.1	21/23.6	279/312.9
	SMR	0.66	1.21	1.07	0.75	0.89	0.89
	95% CI	0.46–0.93	1.01–1.44	0.96–1.20	0.50–1.09	0.55–1.36	0.79–1.00
Lung cancer	Obs/Exp	12/15.8	36/25.4	128.5/84.8	12/12.4	4/5.0	114/104.7
	SMR	0.76	1.42	1.51	0.97	0.79	1.09
	95% CI	0.39–1.32	0.99–1.96	1.26–1.79	0.50–1.69	0.21–2.02	0.90–1.31

SMR, standardized mortality ratio; CI, confidence interval.

^a Observed deaths are not integer values (except for all causes of death) because of correction factors for missing causes of deaths.

Table 5. Standardized mortality ratios of lung cancer by duration of employment and time since first employment

Years of employment		Years since first employment				
		1–10	10.01–20	20.01–30	30.01 +	Total
1–5	Obs/Exp	7.0/7.1	12.1/9.7	40.9/16.6	17.8/15	77.7/48.4
	SMR	0.99	1.24	2.47	1.19	1.61
	95% CI	0.4–2.03	0.64–2.15	1.78–3.36	0.71–1.90	1.27–2.01
5.01–10	Obs/Exp	9.0/9.2	10.1/7.7	11.2/9.7	3.2/7.2	33.5/33.7
	SMR	0.98	1.31	1.15	0.44	0.99
	95% CI	0.45–1.86	0.62–2.4	0.57–2.03	0.09–1.22	0.67–1.37
10.01–15	Obs/Exp	—	—	—	—	34.4/35.1
	SMR	—	—	—	—	0.98
	95% CI	—	—	—	—	0.67–1.35
15.01–20	Obs/Exp	—	—	—	—	45.4/38.3
	SMR	—	—	—	—	1.18
	95% CI	—	0.47–1.51	0.85–2.11	0.64–2.30	0.85–1.56
20.01 +	Obs/Exp	—	—	38.8/34.7	76.7/57.8	115.5/92.5
	SMR	—	—	1.12	1.33	1.25
	95% CI	—	—	0.80–1.54	1.05–1.67	1.03–1.49
Total	Obs/Exp	16.0/16.3	53.2/50.9	120.6/88.0	116.6/93.9	306.5/248.3
	SMR	0.98	1.05	1.37	1.25	1.23
	95% CI	0.56–1.59	0.78–1.37	1.14–1.64	1.04–1.50	1.10–1.38

**Healthy worker survivor effect
(HWSE)**

SMR, standardized mortality ratio; CI, confidence interval.

^a Observed deaths are not integer values because of correction factors for missing causes of deaths.

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Table 6. Relative risk of mortality from lung cancer and non-malignant respiratory diseases for estimated cumulative exposure to respirable TiO₂ dust

Cumulative exposure (mg/

Selective reporting bias

Lung cancer
0–0.73

Conflict of interest

0.73–3.43

3.44–13.19

13.20 +

Linear trend, *p*-value

Non-malignant
respiratory diseases

0–0.8

0.9–3.8

3.9–16.1

16.2 +

Linear trend, *p*-value

52	1.03	0.69–1.55
53	0.89	0.58–1.35
0.5		
40	1.00	Ref.
39	1.23	0.76–1.99
40	0.91	0.56–1.49
39	1.12	0.67–1.86
0.6		

Results of Cox regression analysis.

CLP Expertise conclusion

- Given the methodological bias in dose-response assessment and a statistically significant increase in lung cancer mortality reported in two publications, France has established that **human data are not sufficient to conclude that there is no carcinogenic effect in humans** and cannot contradict the carcinogenic effects observed in rats
- Need to re-analyze existing data and / or a meta-analysis

ECHA RAC decision

- Classification as a **category 2 carcinogen (suspected human carcinogen) by inhalation for TiO₂ in all its forms**
- Inclusion in Annex VI of the CLP Regulation

- Industrial repost

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Date	Country	Organisation	Type of Organisation	Comment number	Pigment, brightener or opacifier in most plastics stability important for outdoor applications.
15.07.2016	Belgium				O2 substance. The (ostat 2014). The gnitude the whole € including polymer
Comment received					
Cerame-Unie, the European including bricks & roof tile table & decorative ware, t accounts for more than 2l					
No cases of pulmonary fib of Dupont "Epidemiologic Dec;30(12):937-42 gave TiO2 as a carcinogen cat. the classification, which w by France.					
Date		Country	Organisation	Type of Organisation	Comment number
15.07.2016		United Kingdom		BehalfOfAnOrganisation	17
Comment received					
This business employs 187 people in Europe. We manufacture wallcoverings. Titanium Dioxide is an important component of our products and it is great concern to us if this material were to be classed as a carcinogen. We have used TiO2 within our products for over fifty years and during this time we have followed all statutory requirements for dust control and we are unaware of any health issues experienced by our employees through exposure to TiO2 in the workplace. The prospect that we may have to label our rolls of wallpaper as containing a carcinogen will potentially cause customers to stop buying our products due to misplaced concerns about a hazard when the potential for exposure to that hazard is very low. Substitution of TiO2 for other materials would not be economic and will raise the cost of products at a time when the whole of Europe does not need any further inflationary pressures. This proposed re-classification if adopted will decimate the DIY industry in Europe					
In st	As ist allready written, there is no evidence, that any product containing TiO2 has caused cancer. Not a single case is known. And the costumers using products containing TiO2 will not come in a situation like mice in a TiO2 dust filled air. TiO2 is bound in liquids and pastes, there is simply no TiO2 dust. Because of this and the fact that there is no sufficient replacement for TiO2 at the time we support any position which does not has to lable products containing TiO2 in liquid or pasty form				
Inverting sector.					
organisation		Comment number			
organisation		10			
problems. product containing more 50i. This means almost r if ist dusty or not. n amount of TiO2 will get					

ACHA RAC response

Attachment to the responses to comments on the CLH report received during public consultation

514 comments have been received as a result of the public consultation from 5 Member-States (Germany, Sweden, Finland, Netherlands) and the remaining from organizations. Among them:

- 176 are related to identity and scope of the dossier (in particular matrix),
- 338 are related to carcinogenicity (human and/or animal data)
- 67 are related to hazard endpoints other than carcinogenicity
- 226 are related to exposure and risk assessment,
- 294 are related to economic impact of the proposed classification

RAC response to comments on carcinogenicity (human data)

RAC independently assessed all the epidemiological studies available up to now, including four studies initially not assessed by DS, but mentioned during PC (Ellis *et al.*, 2010, Ellis *et al.*, 2013, Hext *et al.*, 2005 and Thompson *et al.*, 2016). RAC agreed with the general assessment made by Thompson *et al.* that epidemiological data support a moderate level of confidence for the human evidence and therefore can be used for carcinogenicity risk evaluation. RAC considers that human data do not consistently suggest an association between occupational exposure to TiO₂ and risk for lung cancer as far as no specific TiO₂ micro and nano particle sizes and/or specific physical forms are regarded. However, one cohort study by Boffetta *et al.* (2004) deals specifically with the respirable fraction of TiO₂ dust (calculated from total dust) and suggests that there is no clear dose – response relationship expressed as RR for lung cancer; generally we do not have sufficient amount of relevant studies. In addition, Boffetta *et al.* (2004) indicated in their paper and Hext *et al.* (2005) repeated in their summary paper that the investigated TiO₂ concentrations in the occupational environment generally could be too low to cause lung cancer. Therefore RAC concludes that the animal carcinogenicity studies cannot be overruled.

And finally...

<https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.033.327>

Titanium dioxide

Regulatory process names 5 Translated names 22 CAS names 1 IUPAC names 29 Trade names 176 Other identifiers 135



Substance identity

EC / List no.: 236-675-5

CAS no.: 13463-67-7

Mol. formula: O₂Ti



Hazard classification & labelling



Warning! According to the **harmonised classification and labelling** (ATP14) approved by the European Union, this substance is suspected of causing cancer.



Properties of concern



Suspected to be Carcinogenic

Nanomaterial form



Substance is known to be on the EEA market in nanomaterial form.

Important to know



- Substance included in the [Community Rolling Action Plan \(CoRAP\)](#).

EU classification of CMR substances

Category	Criteria
Cat. 1 A	known to have CMR potential for humans, based largely on human evidence
Cat. 1 B	presumed to have CMR potential for humans, based largely on experimental animal data
Cat. 2	suspected to have CMR potential for humans

Re-analysis of the French data from Boffetta et al (2004)

Type of TiO2 exposure variable		Observed lung cancer	Model 1*		Model 2*		Model 3*	
<i>Binary exposed Vs non-exposed</i>		14	3.75	[0.79-17.9]	4.34	[0.85-22.15]	3.77	[0.79-17.95]
<i>Categorical annual average exposure Vs non-exposed</i>								
]0-0.3] mg/m ³	7	4.04	[0.79-20.63]	5.94	[1.07-32.99]	4.15	[0.81-21.21]
	[0.3-2.4] mg/m ³	3	1.68	[0.26-10.93]	1.64	[0.24-11.11]	1.64	[0.25-10.67]
	>2.4 mg/m ³	4	28.28	[4.57-175.15]	12.97	[1.86-90.74]	27.33	[4.35-171.84]
<i>Continuous annual average exposure (mg/m3)</i>		16	2.10	[1.37-3.22]	1.70	[1.03-2.79]	2.07	[1.34-3.20]
<i>Continuous cumulative exposure (mg/m3-year), 0 lag</i>		16	1.02	[0.97-1.06]	-	-	1.02	[0.97-1.06]**
	5-year lag	9	1.02	[0.98-1.07]	-	-	1.02	[0.98-1.07]**
	10-year lag	5	1.03	[0.99-1.08]	-	-	1.03	[0.98-1.08]**
	15-year lag	1	1.04	[0.98-1.11]	-	-	1.04	[0.98-1.11]**

Hazard ratios and associated 95%-confidence intervals are adjusted for calendar period in Model 1; for calendar period and exposure duration in Model 2; for calendar period, exposure duration and smoking status in Model 3, except for cumulative exposure variable ** adjusted only for calendar period and smoking status in Model 3

Re-analysis of the EU data

International Agency for Research on Cancer



World Health
Organization

Research Project

Reanalysis of TiO₂ human data (RealyTi)

As part of the CLP classification dossier on titanium dioxide, the available epidemiological data were evaluated (ANSES, 2017). Three occupational cohorts were identified: two American cohorts (Ellis et al., 2013, Fryzek et al., 2003) and a

Main conclusions

- Association between cumulative exposure and lung cancer mortality, after correction of the HWSE
- Exposure reduction corresponds to a significant reduction in the number of lung cancer deaths
- The safety of NIOSH REL (2.4 mg / m³) seems questionable

Essential Public Health Operations

- EPHO3: Health protection (environmental, occupational, food safety etc.)
- EPHO10: Advancing public health research to inform policy & practice

Statistiques

La population active suisse est championne en Europe

A fin 2018, la population active (15-64 ans) participant au marché du travail en Suisse a augmenté à 84,2%, contre 81,3% en 2010, juste derrière l'Islande avec 88,7%.

<https://www.24heures.ch/economie/population-active-suisse-championne-europe/story/10701185>

Essential Public Health Operations

- EPHO3: Health protection (environmental, occupational, food safety etc.)
- EPHO10: Advancing public health research to inform policy & practice

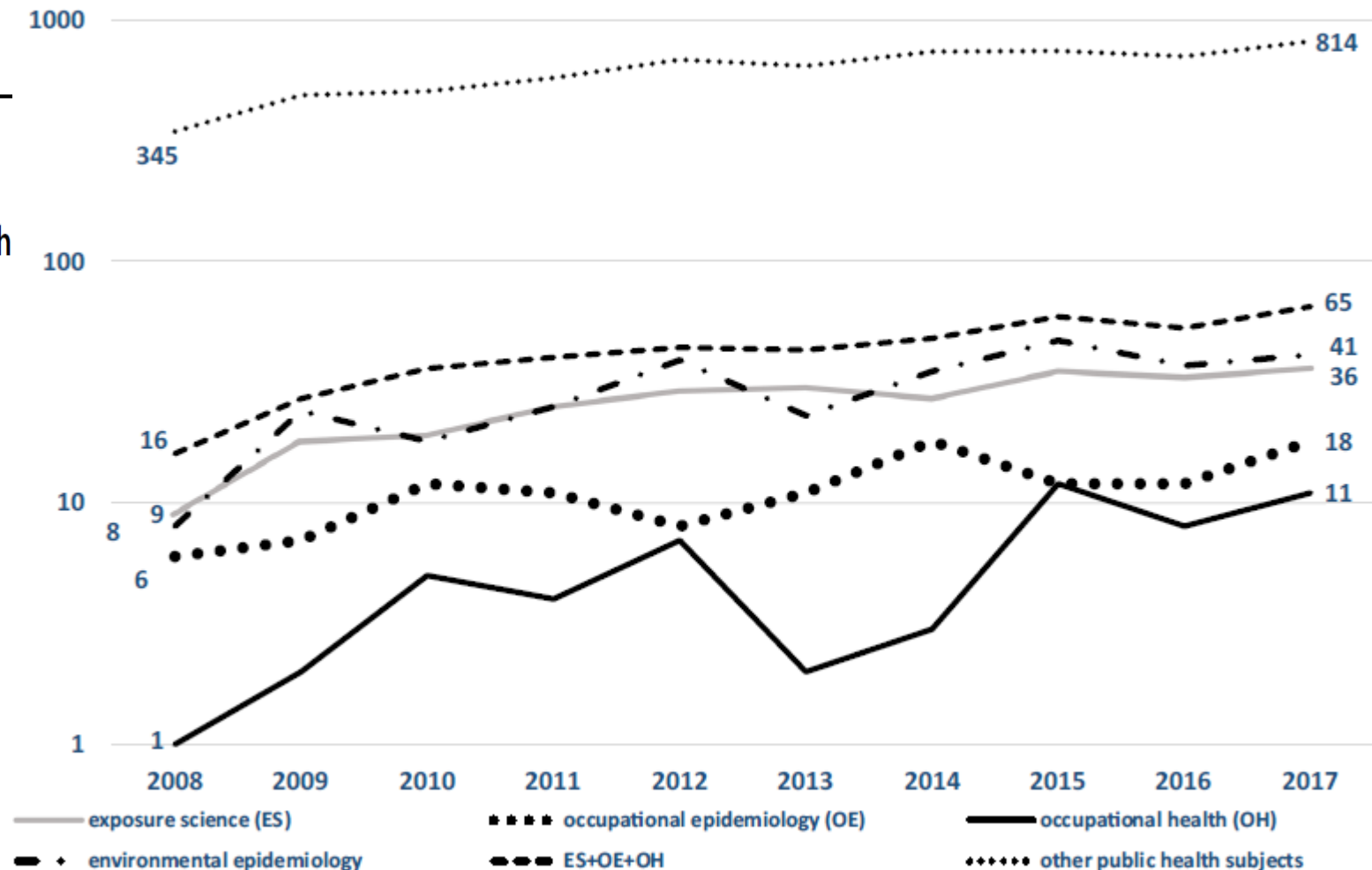
International Journal of Public Health
<https://doi.org/10.1007/s00038-019-01245-w>

ORIGINAL ARTICLE

Healthy worker, healthy citizen: the place of occupational health within public health research in Switzerland

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Fig. 1 Evolution of the number of yearly publications in public health, occupational health and its related disciplines, and environmental epidemiology in the six selected Swiss public health institutions in Switzerland, 2008–2017





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Thank you for your attention !

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