

Responsible development of nanotechnology

ISQ, Oeiras - Portugal 18 de Maio de 2015

Dr Jorge COSTA-DAVID European Commission (DG EMPL/B/3)



EU LEGAL BASIS FOR PROTECTING WORKERS FROM RISKS ASSOCIATED TO NANOMATERIALS

The current EU Occupational Safety and Health (OSH) legal framework covers such risks even if only by default

Coverage provided for by Council Directive 89/391/EEC[1] on the introduction of measures to encourage improvements in the safety and health of workers at work

[1] Official Journal L 183, 29.6.1989 p.1



Namely: Article 1 Object 3. This Directive sha

3. This Directive shall be without prejudice to existing or future national and Community provisions which are more favourable to protection of the safety and health of workers at work.

Scope

1. This Directive shall apply to all sectors of activity, both public and private (industrial, agricultural, commercial, administrative, service, educational, cultural, leisure, etc.).



EMPLOYERS' OBLIGATIONS

Article 5

General provision

1. The employer shall have a duty to ensure the safety and health of workers in every aspect related to the work

Article 6

General obligations on employers

1. Within the context of his responsibilities, the employer shall take the measures necessary for the safety and health protection of workers, including prevention of occupational risks and provision of information and training, as well as provision of the necessary organization and means The employer shall be alert to the need to adjust these measures to take account of changing circumstances and aim to improve

existing situations



2. The employer shall implement the measures referred to in the first subparagraph of paragraph **1** on the basis of the following general principles of prevention: (a) avoiding risks; (b) evaluating the risks which cannot be avoided; (c) combating the risks at source; (e) adapting to technical progress; (f) replacing the dangerous by the non-dangerous or the less dangerous;



3. Without prejudice to the other provisions of this Directive, the employer shall, taking into account the nature of the activities of the enterprise and/or establishment:

(a) evaluate the risks to the safety and health of workers, inter alia in the choice of work equipment, the chemical substances or preparations used, and the fitting-out of work places.



Article 9 Various obligations on employers

1. The employer shall:
(a) be in possession of an assessment of the risks to safety and health at work, including those facing groups of workers exposed to particular risks;
(b) decide on the protective measures to be taken and, if necessary, the protective equipment to be used;



Article 10 Worker information

1. The employer shall take appropriate measures so that workers receive, in accordance with national laws and/or practices which may take account of the size of the undertaking and/or establishment, all the necessary information concerning: (a) the safety and health risks and protective and preventive measures and activities in respect of both the undertaking and/or establishment in general and each type of workstation and/or job;



Article 12 Training of workers 1. The employer shall ensure that each worker receives adequate safety and health training, in particular in the form of information and instructions specific to his workstation or job: -in the event of the introduction of any new technology.

The training shall be:

- adapted to take account of new or changed risks, and
- repeated periodically if necessary.



WORKERS' OBLIGATIONS Article 13

1. It shall be the responsibility of each worker to take care as far as possible of his own safety and health and that of other persons affected by his acts or Commissions at work in accordance with his training and the instructions given by his employer.



European Parliament Resolution

[1] P6_TA(2009)0328. European Parliament Resolution of 24 April 2009 on regulatory aspects of nanomaterials (200S/2208(INI)

Specifically on workers protection, in point 14 of the Resolution, the EP underlined the importance for the Commission and/or Member States to ensure full compliance with, and enforcement of, the principles of Community legislation on the health and safety of workers when dealing with nanomaterials, including adequate training for health and safety specialists, to prevent potentially harmful exposure to nanomaterials



In point 15 of the resolution, the EP called on the Commission to:

evaluate the need to review worker protection legislation concerning, inter alia:

- the use of nanomaterials only in closed systems or in other ways that exclude exposure of workers as long as it is not possible to reliably detect and control exposure,
- a clear assignment of liability to producers and employers arising from the use of nanomaterials,
- whether all exposure routes (inhalation, dermal and other) are addressed;



Challenges to OSH in the EU Strategic Framework on Health and Safety at Work 2014-2020 COM(2014)332



Evaluation of the EU Strategy on Health and Safety at Work 2007-2012 – SEC(2013) 202

• It highlighted Inter alia the need to review objectives, priorities and working methods to adapt the EU policy framework to changing patterns of work, and new and emerging risks

 Challenge: Improving the prevention of work-related diseases

New technologies and new work organization, despite their obvious benefits, can additional entail risks, e.g. nanotechnologies, biotechnologies and green technologies.



Open Invitation to tender No VT/2011/039 <u>http://ec.europa.eu/social/main.jsp?catId=626&langId=en&callId=311&furtherCalls=yes</u>

Study service contract to establish the potential impact of Nanomaterials & Nanotechnology at the Workplace, evaluate the scope and requirements of possible modifications of relevant EU Safety & Health at Work legislation and elaborate a guidance document to accommodate corresponding risks/concerns, with a view to ultimately ensure adequate protection of workers health and safety from risks inherent to exposure to Nanomaterials and/or Nanotechnology use



The subject of the study is threefold:

- To analyse the suitability of the EU-OSH legal framework in its current form relative to Nano specific workplace risks
- To elaborate possible scenarios, individually or, possibly for a number of selected ones, combined
- Elaborate a Guidance document that addresses actual shortcomings in a realistic manner



1. Analyse the suitability of the EU-OSH legal framework in its current form relative to Nano specific workplace risks

- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work
- Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
- Commission Recommendation 670/2003/EC, of 19 September 2003 concerning the European schedule of occupational diseases



3. Guidance document to address shortcomings in a realistic manner (I)

- 1. The types, uses and likely exposures and which workers are more likely to be exposed as well as future exposure trends based on current knowledge.
- 2. The specific information requirements for risk assessment and what are the more significant gaps relative to workplace risk assessment needs (conclusions arrived at under this point may not be immediately 'transferable' but may provide an insight as to which immediately available risk management approaches can compensate for such gaps).
- 3. Identification of types and effectiveness of risk management measures relevant in this context.



3. Guidance document to address shortcomings in a realistic manner (II)

- 4. Based on current knowledge, and to the extent possible, identification of whether the **mode of action** of NMs is similar or different from traditional work based chemicals, *e.g.* whether or not there is an increased risk from the dermal and inhalation exposure routes.
- 5. State of the art regarding measurement and monitoring approaches and techniques, *e.g.* have national or other Occupational Exposure Limits setting bodies any standards in place and/or whether there are already any associated measurement methodologies.



Socio-economic analysis Operating costs and conduct of business

- a) What kind of compliance costs will amendments impose on business?
- **b)** Will they entail stricter regulation of the conduct of a particular business?
- c) Will they lead to the closing down of businesses?
- d) Would some businesses (for example SMEs) cope better or worse than others in a comparable situation?



Innovation and research

- a) Would any amendments stimulate or hinder research and development?
- b) Would they facilitate the introduction and dissemination of new production methods, technologies and products?
- **Specific sectors**
- a) Would the amendments have significant effects on certain sectors?
- b) Would they have specific consequences for SMEs?



The macroeconomic environment What are the overall consequences of any amendments for economic growth and employment?

Employment and labour markets
a) Would the amendments have specific negative/positive consequences for particular professions, specific groups of workers (*e.g.* pregnant workers) or self-employed persons?
b) Would they affect access to the labour market?



In the meantime...

(Problems associated with workplace risk management measures for Nanomaterials)

- Number of nanomaterials is significant
- Paucity of hazard information
- Few nanomaterials studied
- Few long-term studies
- Occupational exposure scenarios ???
- Workers are already exposed



In the meantime (II) ...

http://annhyg.oxfordjournals.org/content/early/2015/04/0 7/annhyg.mev020.abstract





How do you develop risk management guidance?

Worker Protection implies:

- Hazard Identification (should nanos really be deemed harmful?)
- Exposure Assessment (is exposure in real conditions a certainty?)
- **Risk Characterization** (is the hazard real? Will there be exposure?)
- Risk management (procedures to minimize exposure)



Toxicity data:

Adequate → Quant. Risk Assessment → OEL

Suggestive or insufficient → Qualitative or semiquantitative Hazard or Risk Assessment, (Q)SARs → OELs, control banding, performance based exposure control limits



Health-based or risk-based limit values

- Occupational Exposure Limits (OELs)
- Derived No-Effect Levels (DNELs)
- **Precaution-based limit values (NRVs) / Provisionally** useable for risk management?



- A NRV defines a maximum generic level for the concentration of nanoparticles in the workplace atmosphere, corrected for the background particle concentration.
- A NRV is intended to be a warning level to urge for risk management of nanoparticles at the workplace. When exposure levels are exceeded measures should be taken.
- NRVs do not fully guarantee that exposures below the NRV-level are safe.



Time	Hazard Classification	Type of Action
Present	As if	Precautionary principle
Near Future	Likely to be	Diligence
Far Future	Is	Regulatory

	-	-	-	-	-	Table	Tools	Final Report June 2013.doc [Read-Only] [Compatibility Mode] - Microsoft Word
Page Layout	References	Mailings	Review	View	Developer	Design	Layout	
1 1 1	2 1	3 . 1	1 4 1	1		6 1 1	7	、8、1、9、1、10、1、11、1、12、1、13、1、14、1、15、1人===16、1

e 3.3: Summar	y of the legal analy	vsis	
e of the lation	MNMs explicitly covered?	Dependence on other legislation	Main findings
)89/391/EEC	N	Fully applicable	Its provisions cover NMs
98/24/EC	N	Fully applicable	The CAD fully applies to NMs, however the required risk assessment is partially dependent on REACH and CLP
1 /39/EC 2 /15/EC 3 /161/EU	Ν		The Scientific Committee for Occupational Exposure Limits to Chemical Agents in establishing OELs should assess the latest available scientific data
2004/37/EC	N	Dependent on REACH and CLP	The CMD would apply if a NM would be classified as carcinogen or mutagen

🕉 English (U.K.)

	ie Insert Page Lavout References	Mailings Review View Devel	Table Tools Final Report	June 2013.doc [Read-Only] [Compatibility Mode] - Microsoft Word
- - - - -	₩X • 1 • 1 L 1 • 2 • L •			L 9 - 1 - 10 - 1 - 11 L 1 - 12 - L - 13 - I L 14 - 1 Liassiiicu as caiciiiugcii Ul IIIutageii
1 TT	WED 2009/104/EC	z		Annex I (2.5, 2.17, 2.18) covers the emi incidental NMs (PGNP)
13 - 1 - 15	WRD 89/654/EEC	z	Fully applicable	Although WRD does not cover explicit its scope encompasses those workplace: NMs might be present
ις φτοριο St. οι ο 9τ. οι ο Ζτ. οι ο 8τ. οι	PPED 89/656/EEC	Z		The PPED does not specifically mention (on MNMs. However, if the followin conditions are met, the PPED provision be relevant and apply to protection fror risk: • MNMs in the workplace resulting in risk; • impossibility to protect workers from via collective protection measures or work patterns; and • availability of PPE offering protectio such risk
Γ · ι · Ο	CSD 92/57/EEC	z		The Directive implicitly covers the emis PGNP
▲ Page: 72 of 145	words: 48.238 🍝 English (UK.)			10

√. Ⅲ16 The Directive implicitly covers the emissions of The PWD would apply if a NM would be The Directive implicitly covers the emissions of classified as carcinogen or mutagen or breast-fed 5 14 to Final Report June 2013.doc [Read-Only] [Compatibility Mode] - Microsoft Word 1 or harmful . 12 11 L I babies/children. reprotoxic 읅 PGNP PGNP đ **REACH and CLP** Dependent on Layout Design - 0 View Developer Page Layout References Mailings Review Z Z z 4 92/104/EEC 92/85/EEC)2/57/EEC N

Nanomaterials in the Workplace RPA & IVAM | 63 ≣

File Home	a Insert	Page Lavout R	leferences Mailings Review V	Table T few Developer Design	ools Final Report June 2013.de	oc [Read-Only] [Compatibility Mode] - Microsoft Word
	1 · 2		±Z · · · 1 _ · · 2 · L ·	3 . 1 . 4 . 1 . 5 . 1	· 6 L · · 7 · L · 8 · 1	L 9 · 1 · 10 · 1 · 11 L 1 · 12 · L · 13 · 1 L 14 · 1
			Name of the Legislation	MNMs explicitly covered?	Dependence on other legislation	Main findings
			MEID 92/104/EEC	Z		The Directive implicitly covers the emis: PGNP
			YWD 94/33/EC	Z	Dependent on REACH and CLP	The YWD would apply if a NM wo classified as toxic, carcinogenic, cause h genetic damage, or harm to the unborn which in any other way chronically human health
	_		SSD 92/58/EEC	z		The SSD does not specifically mention c
	_					are met, the SSD provisions would a particular workplace where MNMs are u
	_					MNMs in the workplace resultir
	_					USH risk which is identified by assessment mandated by the O
						 impossibility to protect worker this risk via collective pro
	_					measures or altering work pi and
						 relevance of one of the signs { the SSD to the risk in question
Page: 73 of 145	Words: 48.238	🕉 English (U				

File Home Insert	Page Layout References	Mailings Review View	Developer Design La) 3 · 1 L 4 · 1 · 5 · 1	/out • 6 L • 7 • L • 8 • 1	L9.1.10.1.11.L1.12.L.13.1.L14.1.1 <u>5</u> .1
		Name of the Legislation	MNMs explicitly covered?	Dependence on other legislation	Main findings
		MEID 92/104/EEC	z		The Directive implicitly covers the emissions o PGNP
		YWD 94/33/EC	z	Dependent on REACH and CLP	The YWD would apply if a NM would by classified as toxic, carcinogenic, cause heritably genetic damage, or harm to the unborn child o which in any other way chronically affect human health
		SSD 92/58/EEC	z		The SSD does not specifically mention or focu on MNMs. However, if the following condition are met. the SSD provisions would apply to
					 matrix matrix model and the morkplace resulting in al OCH risk which is identified by the risk
	_				assessment mandated by the OSHD;
	_				 impossibility to protect workers fron this risk via collective protection
	_				measures or altering work patterns and
	_				 relevance of one of the signs given in the SSD to the risk in question
		EAD 99/92/EC	z	Fully applicable	EAD applies to situations where nanomaterial might be present in the form of mists or dusts
4 Page: 73 of 145 Words: 48.238	🕉 Endlish (U.K.)				



The Scenarios – problem definition

- Lack of a harmonised definition of nanomaterials
- Lack of harmonised guidance on the safe handling of nanomaterials in the workplace
- Lack of information on the specific physicochemical, toxicological and ecotoxicological properties of NMS
- Lack of information on MNMs in the Safety Data Sheets
- Lack of Occupational Exposure Limits specific to nanomaterials



- **REACH tonnage bands thresholds for information requirement**
- Lack of clarity about the scope of the existing OSH legislation
- Lack of knowledge on how to conduct a suitable on nanomaterials specific Risk Assessment
- Lack of awareness on which Risk Management Measures should be applied in working with nanomaterials

Final Report June 2013.doc [Read-Only] [Compatibility Mode] - Microsoft Word Developer

View Review References Mailings Page Layout Home Insert

+

L

	C2 – Guidance document of a non- binding nature	Introduction of a definition in guidance would result in further confusion for stakeholders and would be non-binding by nature	New harmonised guidelines for helping employers in complying with OSH legislation would be of benefit	This option is neither appropriate nor realisticas a means of obtaining or generating information on NMs
	C1 – Recommended guidelines	Introduction of a definition in Commission Recommendation could be effective, but would be non- binding by nature	At this stage, a Commission recommendation is unlikely to be the most appropriate vehicle for providing guidance to employers-although it may be of benefit in future	This option is neither appropriate nor realisticas a means of obtaining or generating information on NMs
	B2 – Amendment of the CAD	Introduction and adaptation of the recommended definition within the CAD (article 2) would be effective, but could potentially narrow scope of the CAD	Provision within the CAD of a simplified risk assessment procedure to be applied for the safe handling of MNMs may be possible in theory, however, this may not be easily understandable for employers	OSH legislation (including CAD) is not the most appropriate or relevant regulatory mechanism for generation of information
lem area	B1 – "Nano" Directive	It is likely that a nano- directive will provide a comprehensive and harmonised definition for the purposes of the OSH legislation	Provision within the Nanos Directive of a simplified risk assessment procedure to be applied for the safe handling of MNMs may be possible in theory, however, this may not be easily understandable for employers	OSH legislation is not the appropriate vehicle forgeneration of information and, as such, a Nano as such, a Nano Directive is not suited for the identified problem
of the scenarios by prob	A - Baseline	Commission Recommendation on the definition of nanomaterial is expected to be revised in 2014 and would be expected to assist harmonisation	Different guidance documents produced by several international bodies, national authorities and private companies could result in a lack of legal clarity and confusion for employers	REACH Regulation REACH Substance Evaluation OECD Programme Public and private research ECHA guidance for NMs
Table 7.1: Comparison d	Problem area	1- Lack of a harmonised definition	2- Lack of a harmonised guidance on the safe handling of nanomaterials in the workplace	3 – Lack of information on physicochemical, toxicological and ecotoxicological properties of NMs

Page: 130 of 145 Words: 2/48.238 🥸 English (U.K.)

Ŧ

				2	ca culture
Problem area	A - Baseline	B1 – "Nano" Directive	B2 – Amendment of the CAD	CI = Recommended guidelines	uce – Guidance document of a non binding nature
4 - Lack of information on MNMs in SDS	 ISO/TR 13329:2012 Swiss guidelines for SDS for synthetic nanomaterials 	OSH legislation is not the appropriate vehicle for generation of information and, as such, a Nano Directive is not suited	OSH legislation (including CAD) is not the most appropriate or relevant regulatory mechanism for generation of	This option is not appropriate as a means of obtaining or generating information on NMs	This option is n appropriate as means of obtaining generating information on NN
5 - Lack of OELs on NMs	- Private research on DNELs for REACH	for the identified problem OSH legislation is not the appropriate	information OSH legislation (including CAD) is not	This option is not appropriate as a	This option is a appropriate as
	- Public research (MSCAs, SCOEL, JRC) on OELs for dust, ultrafine dust and MNMs - Recommendation of NRVs in the Netherlands	of information and, as such, a Nano Directive is not suited for the identified problem	or relevant regulatory mechanism for generation of information	generating OELs	generating OELs
6 - Tonnage bands thresholds under REACH	No foreseen action.	Nano Directive is not relevant for amending information requirements under REACH	CAD is not relevant for amending information requirements under REACH	This option is not relevant for amending information requirements under REACH	This option is relevant amending information requirements un REACH
7 - Lack of clarity about the scope of the existing OSH legislation	OSHD, CAD and CMD Legal analysis of the EU OSH Framework within this study	A Nano Directive would help in clarifying the requirements for employers	The detailing of a MNM tailored Risk Assessment within the CAD might narrow its scope and add confusion	The provision of guidelines would help in clarifying the scope of OSH legislation	The provision guidelines would h in clarifying the sco of OSH legislation

Final Report June 2013.doc [Read-Only] [Compatibility Mode] - Microsoft Word

Page Layout References Mailings Review View Developer

Home Insert

± 10 + 0 ∰ 10 + 6 ₩

Nanomaterials in the Workplace

Page: 130 of 145 | Words: 2/48.238 | 🕉 English (U.K.)



Potential regulatory and non-regulatory scenarios

- Do nothing
- Non-legislative approach
 - Semi-legal guidance A Commission Recommendation
 - Commission guidance for information only
 - Voluntary agreement
- Legislative approach
 - OSH Nanos Directive
 - Amendment of CAD to explicitly cover nanomaterials





Categorising level of concern

- -Shape
- Solubility
- Persistence
- Dustiness
- Flammability



Concern categories

High concern

Medium-high concern

Medium-low concern

– Low concern



Categorisation of Risk (Control Banding)

Table 4.7: Control Banding: Risk Level = Concern Category x Level of Exposure

		Level of	Exposure	
Concern Category	Low	Medium- low	Medium- high	High
Low	1	1	2	2
Medium-low	1	2	2	3
Medium-high	2	2	3	4
High	3	3	4	4



• Guidance documents available in:

DG EMPL

http://ec.europa.eu/social/main.jsp?catId=716&langId=en

OSHA

https://osha.europa.eu/en/news/eu-safe-use-ofnanomaterials-commission-publishes-guidance-foremployers-and-workers



Thank you !

Dr. Jorge COSTA-DAVID European Commission Directorate-General for Employment, Social Affairs and Inclusion Unit EMPL B3: Health, Safety and Hygiene at Work EUFO 2/188 10, rue Robert Stumper L-2920 Luxembourg +352 4301 32855 jorge.costa-david@ec.europa.eu

