Project title:

Development of a real-time information and monitoring system to support the risk assessment of engineered nanomaterials (ENMs) under REACH

Project Acronym: **NanoMONITOR**

Grant Agreement: **LIFE14 ENV/ES/000662**

Deliverable

DC1. Definition on the starting situation

Dissemintion Level

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Document Information			
Associated action	C1	Definition on starting situation regarding the use of environmental monitoring data under REACH	
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List of acronyms

BRP:	Biocides Products Regulation
ECHA:	European Chemicals Agency
EHS:	Environmental, health and safety
ENM:	Engineering nanomaterial
PEC:	Predicted exposure concentration
ES:	Exposure scenario
NM:	Nanomaterial
REACH:	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals

Summary

Action **C1: "Definition of the starting situation regarding the use of environmental monitoring data under REACH"** belongs to the group of action intended to monitor the advances of the NanoMONITOR project and its impact.

The generation of new and reliable data on concentration of nanomaterials in industrial areas and the environment thanks to the development of the nano-pollutant monitoring station prototype. In this context, the comprehensive picture of the current situation regarding environmental/exposure monitoring data demanded by action C1 is necessary to correctly evaluate the contribution of the project to fill the enormous gap of knowledge when moving from substances in bulk form to particles at the nano scale.

In this analysis of the state of the art, different aspects of the issue have been taken into account, defining the structure of this deliverable:

- ✓ The availability of monitoring data has been estimated thanks to a thorough bibliographic research. The information gathered has been organized and analysed in Section 2. This is the starting point of the action, which will lay the groundwork for the last one.
- ✓ The demand of data under different regulations will be studied in Section 3, a fundamental step for a better understanding of the real need for monitoring data.
- ✓ The experience of stakeholders with the use of measured data on concentrations of ENMs will be surveyed in Section 4.
- ✓ In Section 5, a definition for the lack of data will be built based on different parameter stemming from the analysis of the available data done at the begging.
- ✓ The results of the analysis will be commented in Section 6.

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1. Scope and goal of the deliverable

The main goal of action C1 of the NanoMONITOR project consists in the evaluation of the current use of measured data to evaluate the potential environmental, health and safety risk (EHS) posed by the use of ENMs, with special emphasis on the data concerning the measured concentrations of ENMs in both industrial settings and the environment. This deliverable is the product of this action and contains the results obtained in the undertaking.

The present deliverable **DC1: "Definition on the starting situation regarding the use of environmental monitoring data under REACH"** intends assessing the current existence and use of measured data, as well as evaluating the potential use of this data in the future. In the framework of a project whose key objective is the promotion of the use of ENMs concentration data, this document will establish the current availability of measured data and their use for regulatory purposes, including the incorporation of measured data on the concentration of both bulk forms and nanoforms into the chemical safety report reported upon REACH registration dossier.

The results presented in deliverable C1 are based on the outcomes of the following sub-tasks of action A1:

- ✓ Task C1.1: Evaluation of the availability of environment/exposure monitoring data;
- ✓ Task C1.2: Study of the potential demand of measured data under REACH regulation and relevant EU environmental regulation;
- ✓ Task C1.3: Characterization of the current use of environmental/exposure monitoring data under EU environmental regulation
- ✓ Task C1.4: Definition of the current lack of data

Based on the above, this deliverable contains:

- Maps of Europe reflecting the availability of data for relevant regions
- A detailed list of the current demand of measured data
- A quantification of the levels of use of measured data
- An analysis of the current lack of monitoring data.

In addition, as a result, an inventory of these data was developed, and results presented in this deliverable, recompiled into Microsoft® Excel spreadsheets.

2. Availability of data

To evaluate the availability of the monitoring data **an analysis of the state of the art was carried out** by searching publications, guides, databases and direct measures from monitoring campaigns conducted by members of the consortium. For each source, parameters as nanoparticle, life cycle stage, activity, action, product, substance characteristics, room conditions, personal protection, exposure and measurement were stored in a database with comparison and analysis purposes.

2.1. Database of collected data for worker's exposure

The first action within the task group encompassing action C1 has been the collection of all available measured information, and its organization into a database according to the parameters included in **Table 1**.

Table 1: Parameters of the created database

Scenario Type	
Nanoparticle	
Life cycle stage	
Activity	
Action	
Product	
Substance characteristics	Physical state
	Primary particle size (nm)
	Shape
	Substance emission potential
Room conditions	Volume, m^3
	Ventilation Type
	Type of local ventilation, at source
Personal protection, hygiene and health evaluation	Personal protection equipment (PPE)
	Level of effectiveness of the PPE
Exposure	Duration
	Time in direct contact
	Exposure pattern
	Frequency of the activity
	Distance from the source to the breathing zone
Measurement	Instrument
	Model
	Type of measure
	Size range
	Period
	[Background]
	[ENMs]
	Units
Release	

These data have been analysed and quantified. In addition, a statistical analysis of the measures has been carried out. The information corresponding to the background concentration and the measured concentration of each scenario has been collected, and the

increment of nanoparticles for each of the scenarios collected in the database has been calculated.

Once these increments have been calculated, two new tables have been created. They show the relationship between the type of nanoparticles and the process. In this way, it has been possible to obtain the exposure of each nanosubstance as a function of the process in which it is used, and vice versa. **Figure 1** shows some examples of the results obtained.

Apart from representing the individual graphical results for each type of process and each nanomaterial, two summary tables have been prepared, one with all the information corresponding to the processes and another one with all the information corresponding to the nanomaterials and they can be consulted in the EXCEL ™ document annexed to this deliverable.

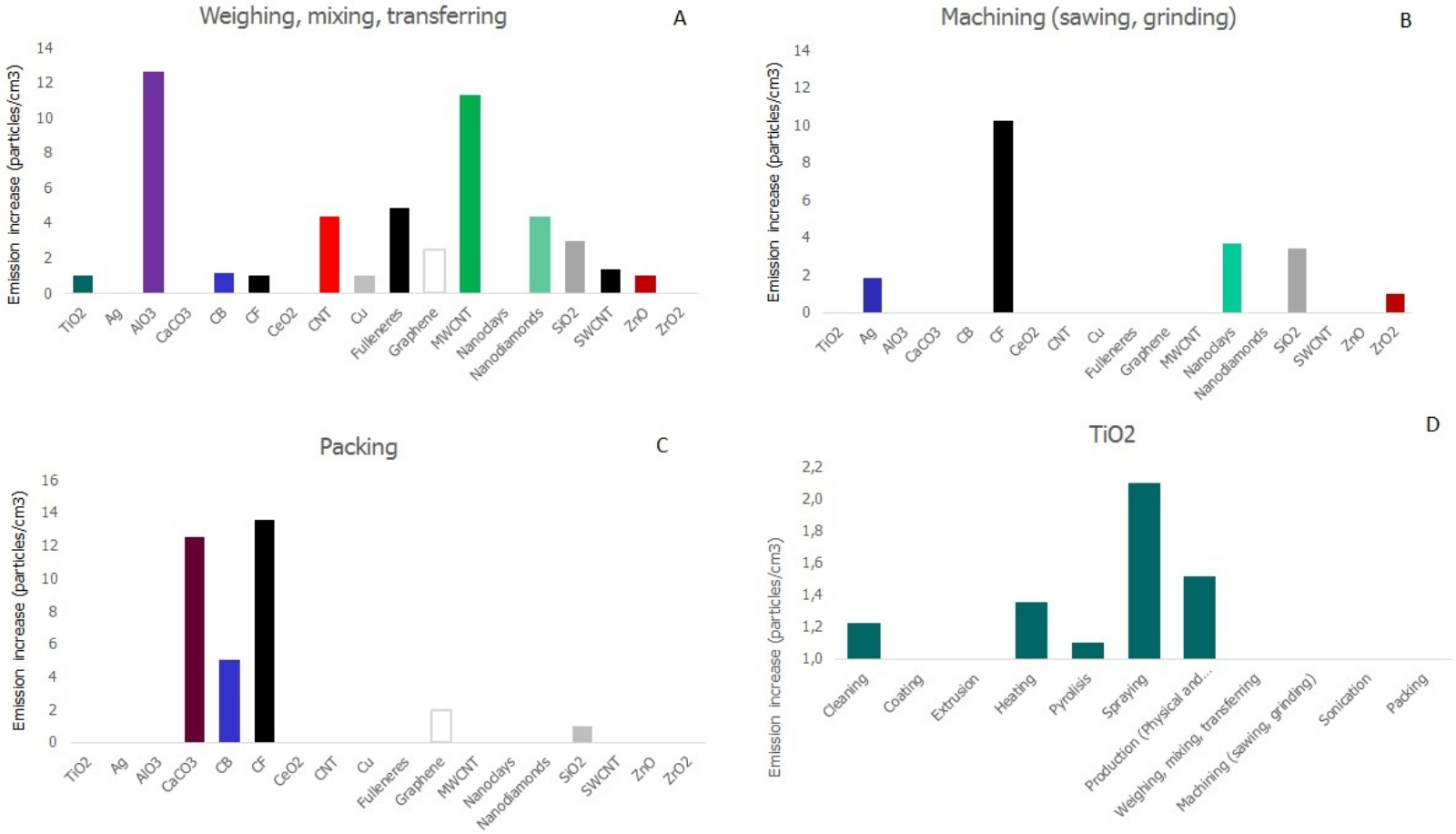


Figure 1: Examples of the results of the analysis for the process of weighting (A), machining (B) and packing (C) and for all process in Titanium Dioxide (D)

2.2. Database of collected data for environmental release

The second part of the task consists of a second database of measured concentrations, on this occasion corresponding to the environmental release. In this case, data are the outcome of an extensive and detailed bibliographic search exclusively.

In order to quantify and classify the data obtained, they have been organized according to the following criteria:

- Nanomaterial
- Environmental compartment
- Predicted Environmental Concentration (PEC) value
- Range

The data corresponding to the environmental release of nanomaterials are much more scarce in the bibliography than those corresponding to worker exposure analysed in the previous section. In addition, there are no direct measures alone. The result is a database for environmental risk considerably less extensive than the one built for workers' exposure.

The database has been divided into two sections: one is a collection of data on the release of nanomaterials into the environment, while the other one collects the release data to the urban compartment. In the case of urban, in addition to the criteria stressed above, have been also taken into account the source of emission and the measurement equipment.

2.3. Maps of release of nanomaterials in Europe

The databases built in the previous tasks were reviewed and referred to the country where the emission took place. Once this was done, the data from the database were processed and air, soil and water release statistics for each nanomaterial were obtained as a function of the country. An example of the result of this statistical analysis is depicted in . After the analysis of the two databases of section 2.2, two maps of Europe have been filled with data on the release of nanomaterials to the environment and to urban areas respectively.

In **Figure 3**, the data on PECs and environmental release data available for the European countries are shown. As it can be seen, data exists only for four countries in Europe. From the perspective of nanomaterials, titanium dioxide (TiO_2) and silver (Ag) are the most measured compounds.

Error! Reference source not found. shows the results for urban environment data. In this compartment, there are more available studies, giving information on air quality levels both in cities and the countryside. The data cover most of the countries of the European Union and some of them are summarized in the table above, which shows nanoparticle concentrations in urban areas, roadside and background levels for different cities of Europe. According to these data, Birmingham, Milan, Zurich, Barcelona and Leicester are the cities with the higher concentration of nanoparticles.

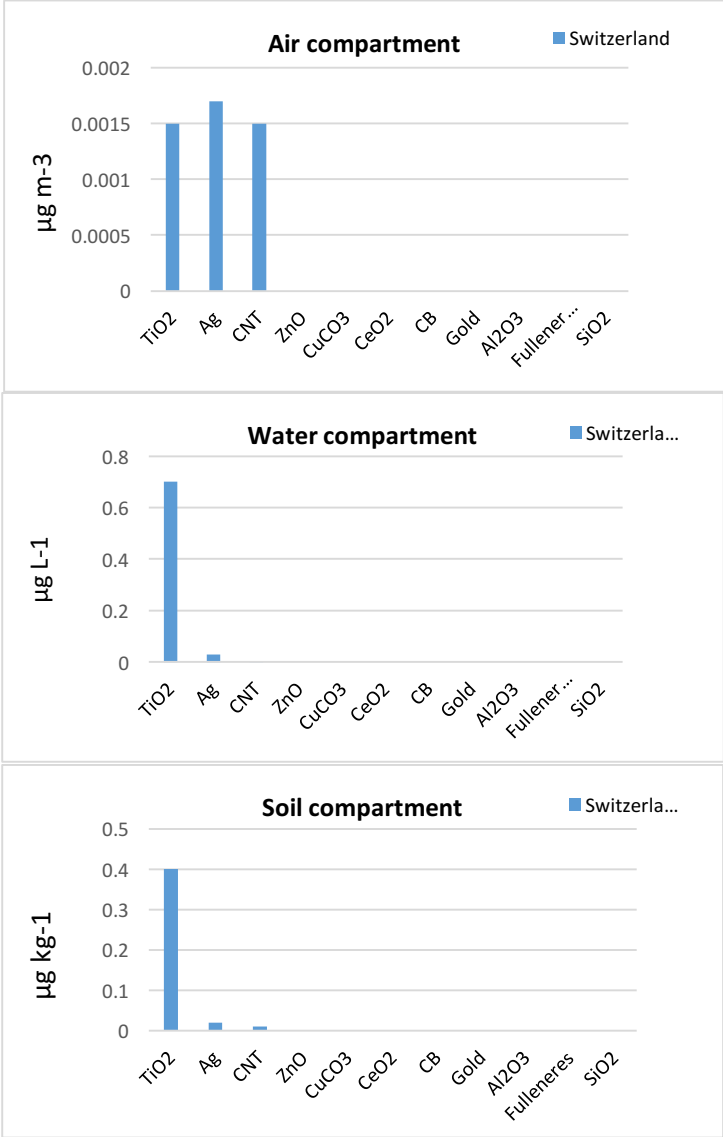
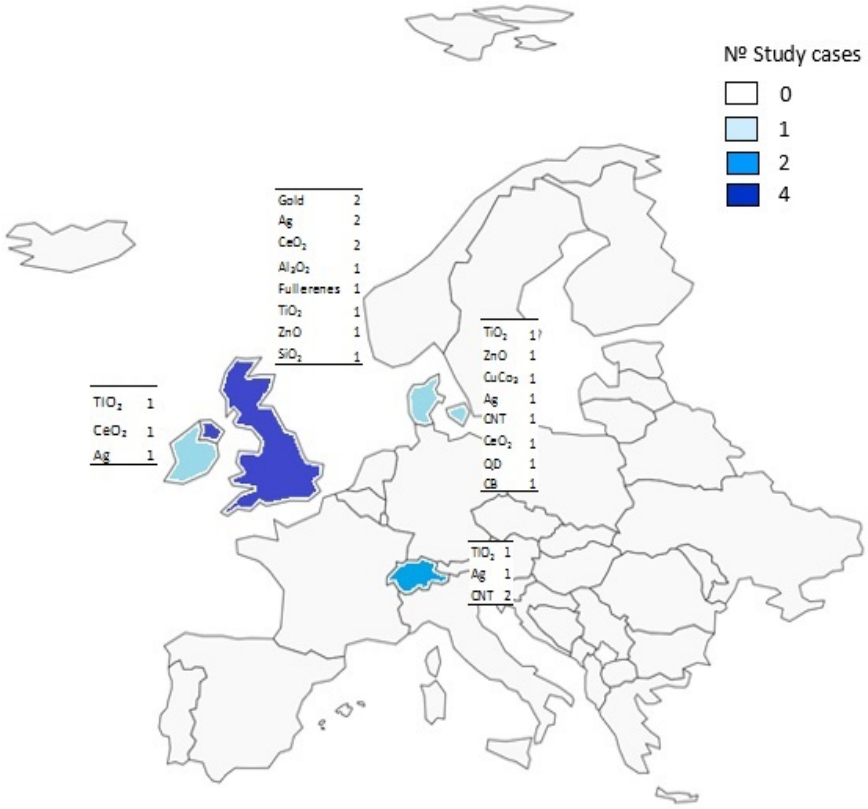
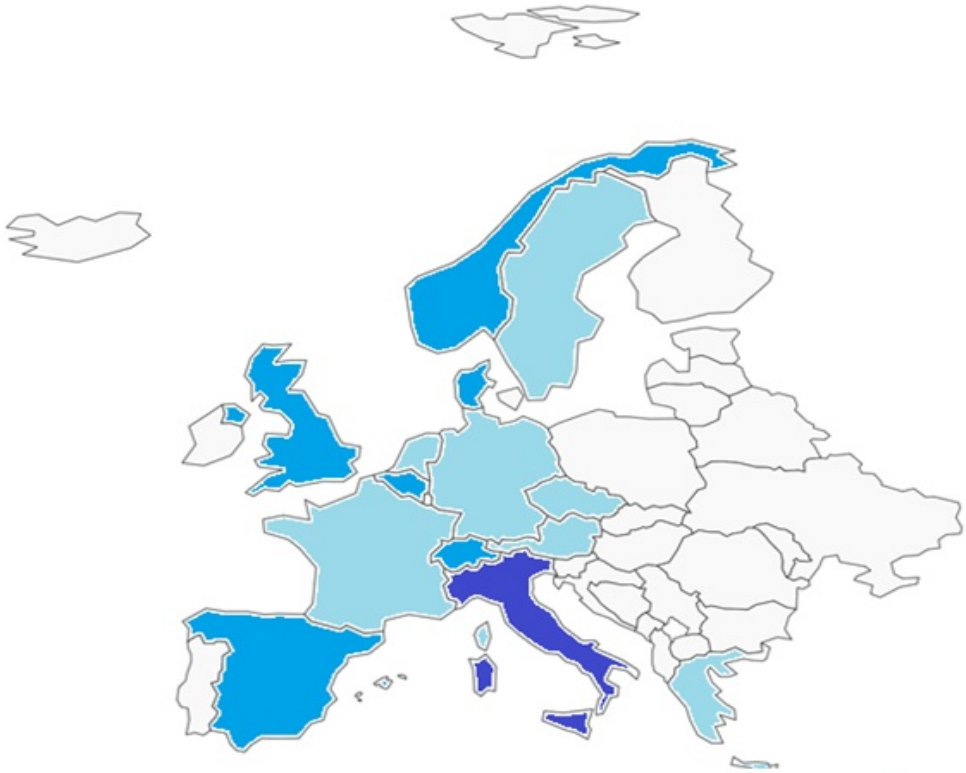


Figure 2: Environmental release of different nanomaterials in Switzerland



		TiO_2	Ag	CNT	ZnO	$CuCO_3$	CeO_2	CB	Gold	Al_2O_3	Fulleneres	SiO_2
Ireland	Air, µg m^{-3}	0,00015	0,0017				0,008					
	Water, µg L^{-1}	1,45	0,03				0,024					
	Soil, µg kg^{-1}											
UK	Air, µg m^{-3}											
	Water, µg L^{-1}	24,5	0,01		76		0,001		0,14	0,002	0,31	0,0007
	Soil, µg kg^{-1}	1030	1,45		3190		10		20,4	0,01	44,7	
Switzerland	Air, µg m^{-3}	0,0015	0,0017	0,0015								
	Water, µg L^{-1}	0,7	0,03	0,0005								
	Soil, µg kg^{-1}	0,4	0,02	0,01								
Denmark	Air, µg m^{-3}	0,0007	0,000007	0,000042	0,00004	0,00002	0,0001	0,2				
	Water, µg L^{-1}	0,00027	0,000015	0,000001	0,00045	0,002	0,000004	0,5				
	Soil, µg kg^{-1}	1,5	0,024	0,083	0,12	60	0,17	1500				

Figure 3 European predicted environmental exposure at natural compartments.



		Urban, nº/cm³	Roadside, nº/cm³	Background, nº/cm³
Germany	Leipzing		18000	9500
	Essen		18000	
	Erfurt			26000
	Augsburg			12000
Spain	Barcelona	11400	59500	17400
	Huelva			17500
	Santa Cruz de Tenerife			12000
	Madrid			7000
Greece	Athens		22000	
Belgium	Antwerpen	15000		15000
Finland	Lahti		39500	11000
	Helsinki	4000	15000	
Italy	Roma		46000	
	Milan		82900	26000
France	Strasbourg		39500	
Denmark	Copenhage	8500	19500	
Netherlands	Utrech		39000	15000
	Amsterdam		30000	
	Alkmaar			26000
Sweden	Stockholm			11000
Czech Republic	Prague		36000	7200
Austria	Vieena		26000	10500
	Salzburg		30000	
	Graz		21000	
	Linz		22000	
Switzerland	Zurich	10000	80000	35000
	Lugano			16000
	Bern		27500	
UK	London		21000	11000
	Birmingham		170000	22000
	Leicester		63000	31000
	Cambridge		26000	9000
	Manchester			26000
Europe			38200	16200

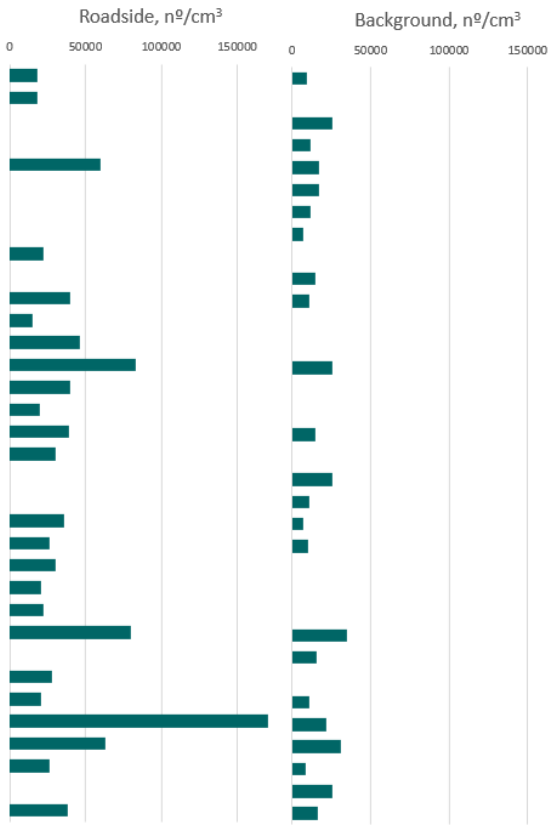


Figure 4: European predicted environmental exposure at human compartments.

3. Potential demand of measured data

The potential risks for human health and the environment associated with the production and use of ENMs are cause of concern and the subject of an intense debate. In this context, question arises as to whether existing regulation is appropriate to address the nanotechnology and nanomaterials issues and what should be done to fill the existent regulatory gaps when it comes to their specific applications. The main limitations seem to be the lack of toxicological data and the difficulties encountered when trying to establish threshold values for occupational exposure limits due to the scarcity of existing methodologies.

The approach adopted by the Commission of the European Communities has been of "incremental" type, which means that existing laws have been adapted to nanotechnologies and sometimes amended to deal with nanomaterials[1]. Task C1.2 develops under this scope and deals with the **characterization and quantification of the demand of specific measured data by the main different existing regulations concerning the protection of human health and the environment from pollutant**, even when the problem of ENMs is not specifically addressed and they are referred to chemical products in general (as it is the case in REACH regulation, for example).

In the following sections the reader will find details on the methodology used and the results obtained.

3.1. Methodology

The objective of the second task of action C2 is to estimate the current demand of measured data in different regulatory frameworks. The methodology used to achieve that is based on a thorough analysis of the different existing regulations on chemical products in the different industrial sectors.

The demand for data and direct measures in the European legislation is almost completely covered by the physico-chemical, toxicological and ecotoxicological properties of the substance, and only in some cases information related to the exposure to the substance and, more precisely to its concentration, is required. The information that has been taken into account in the search is not only limited to direct measures of concentration of ENMs in workplaces and in the different environmental compartments, but also to other quantities strictly related to them. In particular, we considered:

- ✓ Data on concentration of ENMs at workplaces;
- ✓ Data on concentration of ENMs in water;
- ✓ Data on concentration of ENMs in air;
- ✓ Data on concentration of ENMs in soil;
- ✓ Data on release of ENMs to water;
- ✓ Data on release of ENMs to air;
- ✓ Data on release of ENMs to soil;
- ✓ Persistence of the substance in soil and sediment;
- ✓ Biodegradability of the substance;
- ✓ Bioaccumulation potential;
- ✓ Bioconcentration factor;
- ✓ Mobility in soil.

[1] S. F. Hansen and A. Baun, European regulation affecting Nanomaterials – Review of limitations and future recommendations, Dose-Response 10, 364-383 (2012)

According to what we mentioned at the beginning of the section, regulations addressing directly the issue of nanotechnology are not the only ones that have been taken into account in the study. This stems from the fact that the idea behind this action encompasses also the estimation of the *potential* request for direct measures once the legislation in use for chemicals in the different sectors is extended and applied to substances at the nano scale.

The analysis of the legislation comprehended the following criteria:

- ✓ The identification of the subject responsible for providing the measured data: if a manufacturer, a competent authority of the state member of the European Community, an article producer, an exporter/importer, etc.
- ✓ The type of data: direct measures of concentrations (occupational or environmental) or other quantities strictly related with their estimation
- ✓ How the data is provided: to whom it must be communicated by the responsible subject and how, that is the name of the report if known, its section or annex.
- ✓ Where the data is asked for: the exact part of the regulation where the measured data is required (chapter, section, article, annex, etc.).

3.2. Results

In **Table 2** a list of the regulations analysed during action C2.1 is shown, together with a brief description.

Table 2: List of the legislation analysed to estimate the current demand for measured data.

Regulation:	Description:
REACH[2]	REACH is a regulation of the European Union, adopted to improve the **protection of human health and the environment from the risks that can be posed by chemicals**, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances to reduce the number of tests on animals.
PRTR[3]	The European Pollutant Release and Transfer Register (E-PRTR) is the Europe-wide register that provides easily accessible key **environmental data from industrial facilities** in European Union Member States.
Directive 2008/50/CE of the European Parliament and Council[4]	The new on **ambient air quality and cleaner air for Europe** entered into force on 11 June 2008.
Regulation (EC) No 1223/2009 of the European Parliament and Council[5]	Establishes the standards for **cosmetic products** that are available on the market. It was the first major piece of legislation to be amended in Europe: was adapted in 2009 in order to comprise nanomaterials.
BRP [6]	The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of **biocidal products**, which are used to protect humans, animals, materials or articles

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:en:PDF
[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:033:0001:0017:EN:PDF
[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:152:0001:0044:en:PDF
[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF
[6] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:en:PDF

	against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

The result of the analysis performed is shown in **Table 3**, where the information found have been organized and compiled.

Table 3: Result of the analysis of the different existing regulations for substances.

Regulation	Who	Type of data				How to provide the data	Where it is asked for
		Concentration in water	Concentration in air	Concentration in soil	Concentration at workplace		
REACH	Article producers and article importers	-	-	-	Occupational exposure limit values	Safety Data Sheet (8.2)	Annex II
		-	-	Persistence and biodegradability	-	Safety Data Sheet (12.2)	
		-	-	Bioaccumulative potential	-		
		-	-	Mobility in soil	-		
		Bioaccumulation potential	-	-	-	Safety Data Sheet (12.3)	Annex XIII
		Bioconcentration factor	-	-	-		
		-	-	-	Occupational exposure limit values	Chemical Safety Report	Article 7(1)
		PEC	PNEC	-	-		Article 7(2)
PRTR - Regulation (EC) N. 166/2006 of the European Parliament and of the Council	Facilities and installations	Release to water (kg/year)	Release to air (kg/year)	Release to soil (kg/year)	-	Report of pollutant release and transfer data by installations (Section 2 - Release Data) sent to competent authorities	Article 5
		Accidental release to water (kg/year)	Accidental release to air (kg/year)	Accidental release to soil (kg/year)	-		

		Total off-site transfer of hazardous waste (kg/year)				Report of pollutant release and transfer data by installations (Section 3 - Transfer Data) sent to competent authorities	
		Total off-site transfer for waste-water treatment (kg/year)					
		Accidental off-site transfer for waste-water treatment (kg/year)					
	CE Member States	Release to water (kg/year)	Release to air (kg/year)	Release to soil (kg/year)	-	Data are sent electronically to the EEA (European Environment Agency) and by CD ROM to the Commission after validation.	
		Accidental release to water (kg/year)	Accidental release to air (kg/year)	Accidental release to soil (kg/year)	-		
		Total off-site transfer of hazardous waste (kg/year)					
		Total off-site transfer for waste-water treatment (kg/year)					
		Accidental off-site transfer for waste-water treatment (kg/year)					
Directive 2008/50/CE of the European Parliament and of the Council	Member states	-	Concentration of contaminants in air	-	-	Data are sent to the Commission and made available for the public, environmental organizations, consumer organizations, health-care bodies, relevant industrial federation.	Chapter V (Information and Reporting), Articles 26 (Public Information) and 27 (Transmission of information and reporting)
BRP - Regulation (EC) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products	Producers	-	-	-	Exposure data		Annex II, Title I, Section 7 (Specified in Annex VI)
		Degradation, hydrolysis, biodegradability, absorption/desorption, biodegradation	Phototransformation, fate and behavior	Degradation, accumulation in sediment, accumulation in soil, adsorption/desorption, mobility	-	IUCLID Active substance dossier – Section 5	Annex II, Title I, Section 10

Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products	Manifacturers		"The possibility of secondary exposure by routes other than those resulting from direct application should also be considered (e.g. non-intended inhalation of sprays, non-intended ingestion of lip products, etc.)."	-	-	Cosmetic Product Safety Report (to be sent to the competent authorities of Member States), Part A, Pt. 6: Exposure to the cosmetic product.	Annex I
	Member states	-				Data provided from manufacturers are communicated to the Commission of the European Communities, that must validate the Safety Reports.	

4. Characterization of the current use of data

In the previous section, we identified where, in different pieces of regulation, measured data of exposure levels and/or of the release of pollutant to the environment are specifically demanded, and how the subjects of interest are supposed to provide them. As already mentioned, the analysis included also cases not concretely related to ENMs, but, more in general, to chemical pollutant, and that in the future could be extended to substances at the nanoscale.

On the other hand, this section focuses on the third task of action C1, that is the **characterization of the current use of these data** for regulatory purposes. Establishing direct contact with companies, research bodies and industrial association related to the use of ENMs, the type of data included in chemical safety reports, registration dossiers or analogous documents have been identified and the results collected in a Microsoft Excel spreadsheet and analysed.

The outcomes of the tasks are reported in the following subsections.

4.1. Methodology

The first step of the task consisted in building a survey to be sent to the contact lists of all the members of the consortium by email. In order to reach as many stakeholders as possible, the survey, hosted by the SurveyMonkey web site, has also been published on the web page of the NanoMONITOR project and disseminated on specialized social networks' groups and internet forums. Considering all the members of the consortium, we estimated that we have been able to reach more than 230 contacts of interest.

Unfortunately, this method for collecting responses proved not to be very effective and a more direct action was necessary such that, in addition, we contacted by phone 55 companies and research bodies in order to obtain a more direct feedback on the project development.

Below, the content of the survey and a summary table containing our attempts of direct contact and the responses obtained (**Table 4**) are shown.

Study of the potential demand and characterization of the current use of data

Is your company producing or using nanomaterials?

- ○ Producer
- ○ User

Which sector does your company belong to?

Do you have to provide data about the release of the nanomaterials to the environment and/or worker exposure?

- ○ Yes
- ○ No

Under what legislation/regulation is this carried out?

- ○ REACH regulation
- ○ IPPC (Integrated Pollution Prevention)
- ○ IE (Industrial Emission directive)
- ○ Other (Please Specify)

What kind of data do you send to the regulatory body?

- ☐ Identity of the manufacturer and the substance
- ☐ Information on the manufacture and uses of the substance
- ☐ Classification, labeling and use guidelines
- ☐ Chemical physical information of the substance obtained from studies
- ☐ Toxicological and ecotoxicological information
- ☐ Size of the company and annual volume of production
- ☐ Sources of emission of the installation and atmospheric controls
- ☐ Type and magnitude of planned emissions of the installation

Figure 5: Content of the survey hosted by the SurveyMonkey website (https://es.surveymonkey.com/r/NXC32XH).

Table 4: summary table of direct contact attempts and replies obtained.

Total number of email sent	+230	
Responses	**25**	
Total number of phone calls	55	
Results of the calls	Answered	**13**
	Wrong number	2
	Out of the office	8
	Not interested	20
	Not answered	7
	In a meeting	13
	Asked to answer by email	2
	Dismissed	1

4.2. Results of the on-line survey

As already mentioned at the beginning of the section, we obtained 25 responses to the online survey. The table below summarizes the information collected question by question.

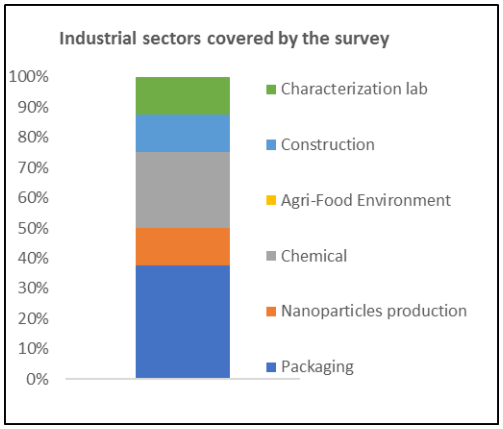
Table 5: Summary table of the responses obtained to the on-line survey question by question.

Q1	**Is your company producing or using nanomaterials?**	
	No answer	4
	User	17
	Producer	4
Q2	**Which sector does your company belong to?**	
	Research	10
	Industrry	15
Q3	**Do you have to provide data about the release of the nanomaterials to the environment and/or worker exposure?**	
	No	15
	Yes	9
	No answer	1
Q4	**Under what law is carried out?**	
	REACH	12
	IE	1
	Other	3
	No answer	9
Q5	**What kind of data send to the regulatory body?**	
	Identity of the manufacturer and the substance	4
	Information on the manufacture and uses of the substance	7
	Classification, labeling and use guidelines	5
	Chemical physical information of the substance obtained from studies	6
	Toxicological and ecotoxicological information	7
	Size of the company and annual volume of production	5
	Sources of emission of the installation and atmospheric controls	4
	Type and magnitude of planned emissions of the installation	1
	No answer	14

As it can be seen in Figure 5, question 2 includes a free text field where it can be specified if the respondent belongs to research or to industry, and also the industrial sector can be pointed out. The 15 responses that we grouped under "Industry" in question 2 are detailed in the following table:

Table 6: Summary of the industrial sectors of Q2.

Q2: Industry	
Packaging	3
Nanoparticles production	1
Chemical	2
Agri-Food Environment	1
Construction	1
Characterization lab	1
Not specified	5



The 3 responses grouped under “Other” in question 4 are the following:

Table 7: Summary of the “Other” responses to Q4.

Q4: Other	
Worker, consumer	1
DLGS 81/2008	1
Not specified	1

Figure 6 shows a graphical representation of the outcome of the on-line survey for the first four questions, while in **Figure 7** the information relative to the type of data sent to the regulatory bodies is shown.

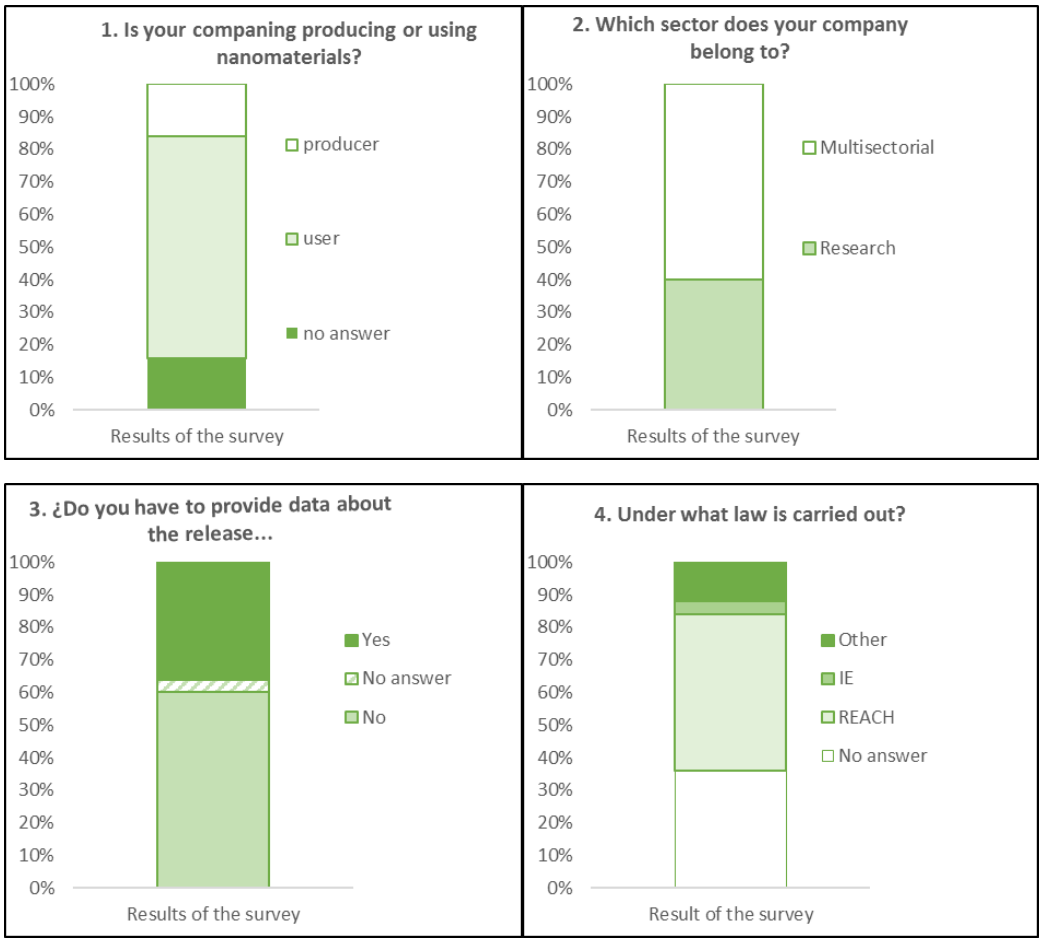


Figure 6: Graphical representation of the data collected through the on-line survey.

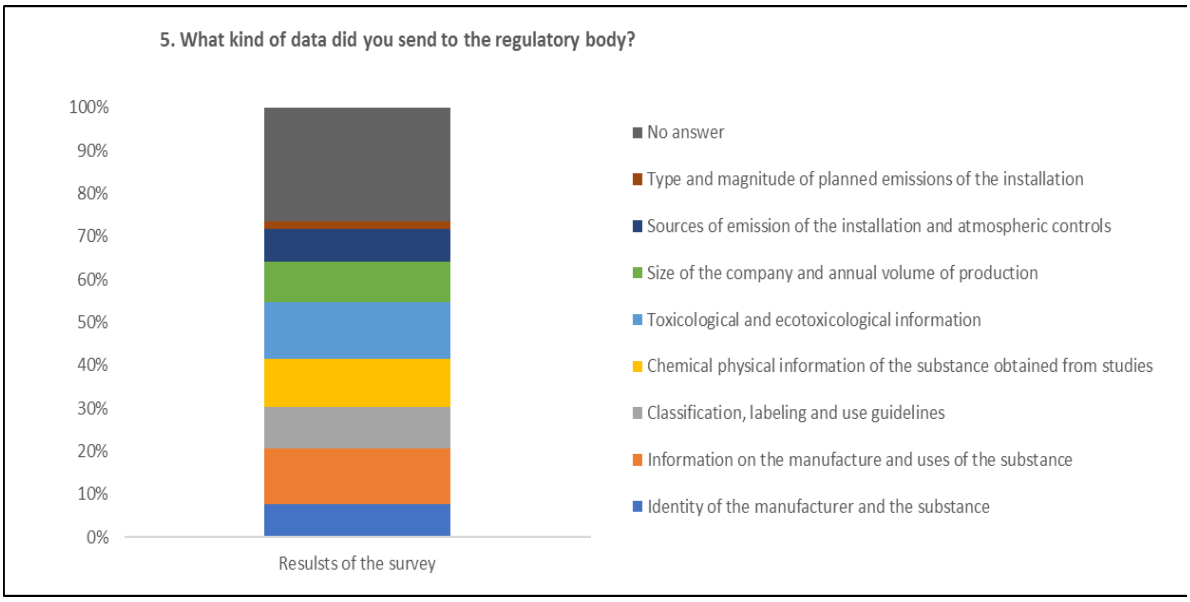


Figure 7: Graphical representation of the results of Q5 in the case of the on-line survey.

4.3. Results of the telephone survey

In the second phase of this task we opted for a more direct action and started calling companies by phone, describing the project and interviewing them. We made a total of 55 calls. The result of the action is detailed in the figure below.

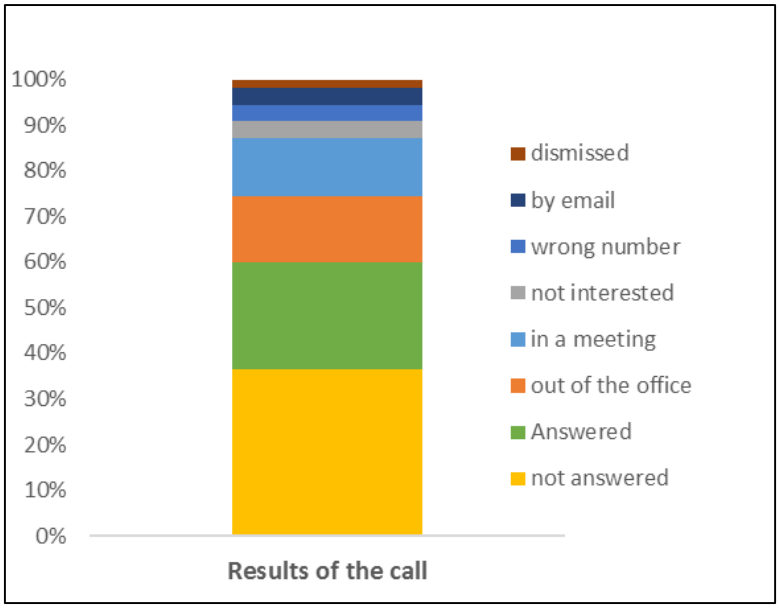


Figure 8: Result of the 55 phone calls made.

As in the previous section, we summarized the information collected by phone in **Table 8**, which is graphically shown in **Figure 9** and **Figure 10**. In particular, **Figure 10** shows the type of data our phone contacts had to send to the regulatory bodies.

Table 8: Summary table of the data collected through the phone calls.

Q1	**Is your company producing or using nanomaterials?**	
	No answer	9
	User	3
	Producer	0
Q2	**Which sector does your company belong to?**	
	Research	2
	Industrry	1
	No answer	9
Q3	**Do you have to provide data about the release of the nanomaterials to the environment and/or worker exposure?**	
	No	2
	Yes	1
	No answer	9
Q4	**Under what law is carried out?**	
	Other	1
	No answer	11
Q5	**What kind of data send to the regulatory body?**	
	Chemical physical information of the substance obtained from studies	1
	Size of the company and annual volume of production	1
	No answer	11

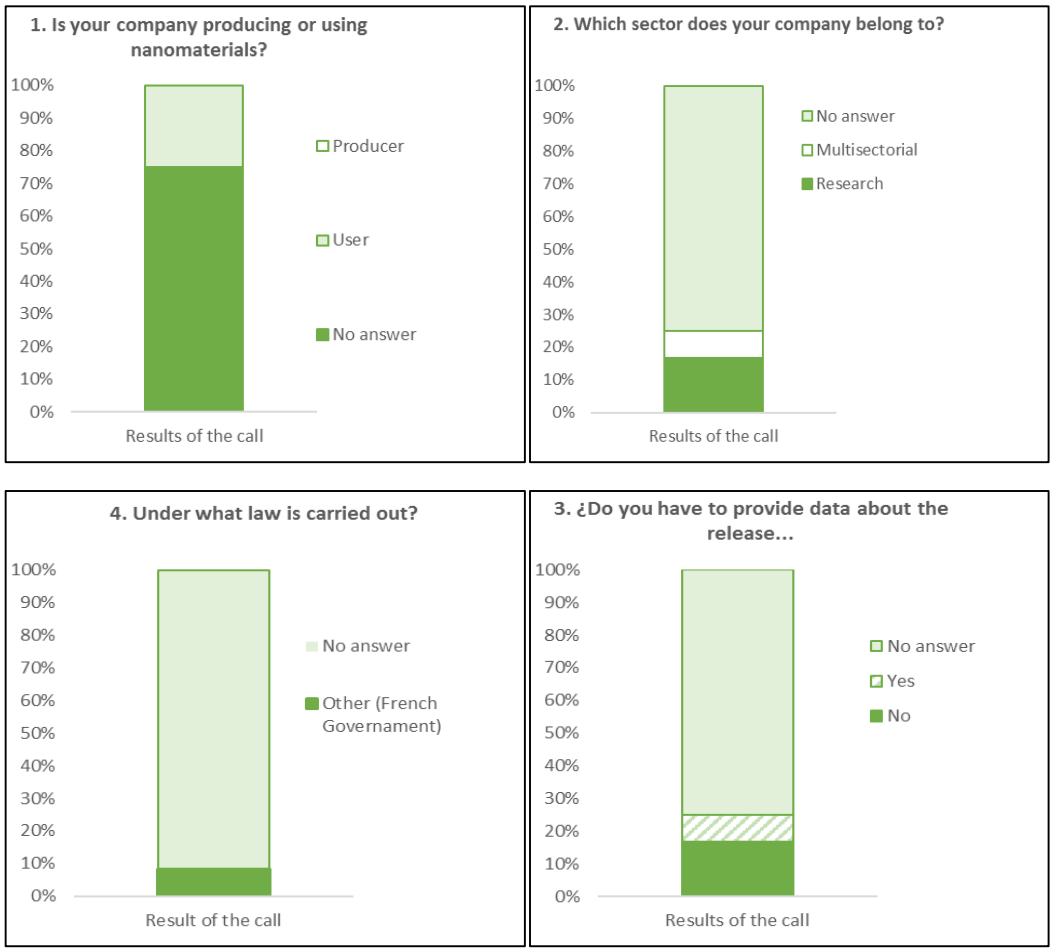


Figure 9: Graphical representation of the data collected through the phone calls.

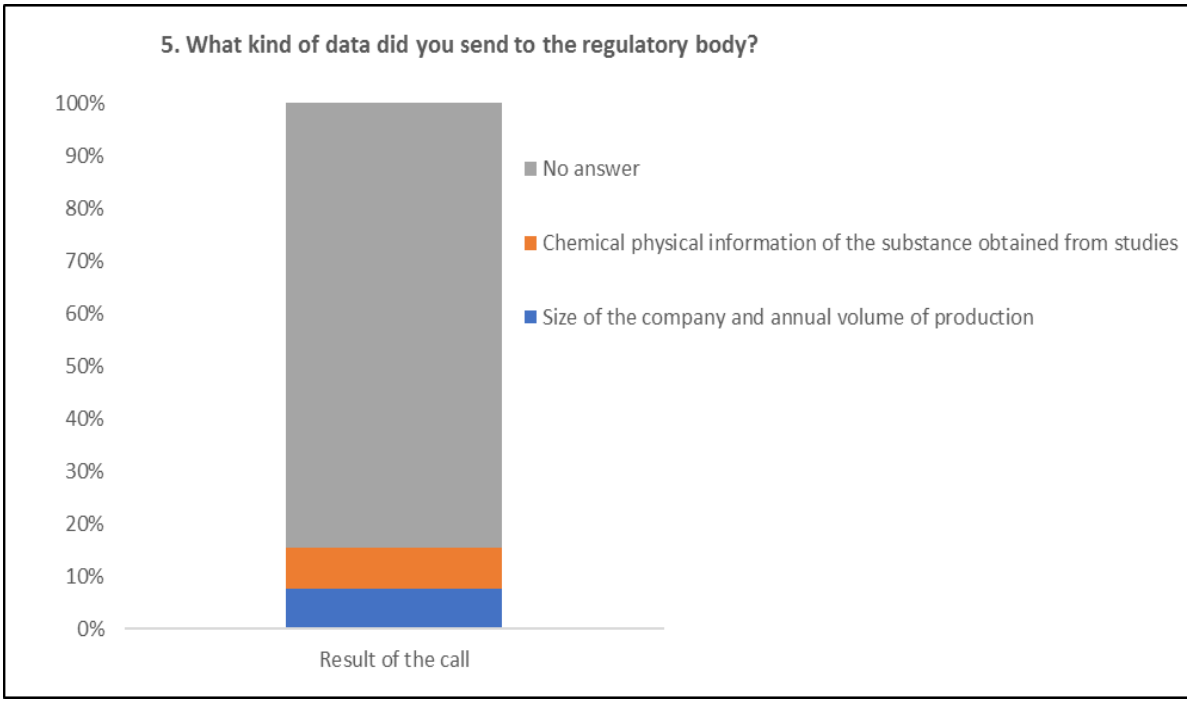
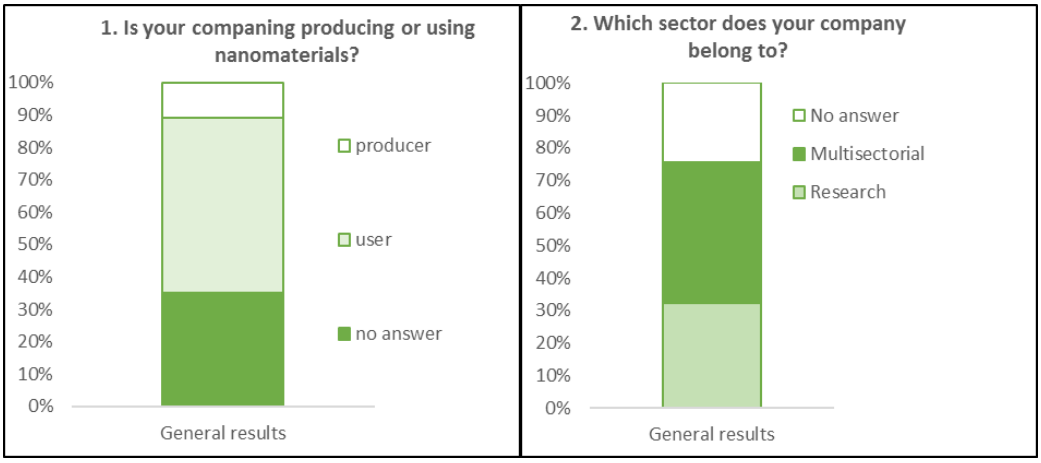


Figure 10: Graphical representation of the results of Q5 in the case of contact by phone call.

4.4. General results

This last section is to show the general results of the third tasks of action C1. This is achieved putting together the information collected by means of the on-line survey and the data collected through the phone calls. **Figure 11** and **Figure 12**. As it is clear from the responses to question 3, most the stakeholders who decided to answer do not need to provide data on concentrations to the competent authorities for regulatory purporse.



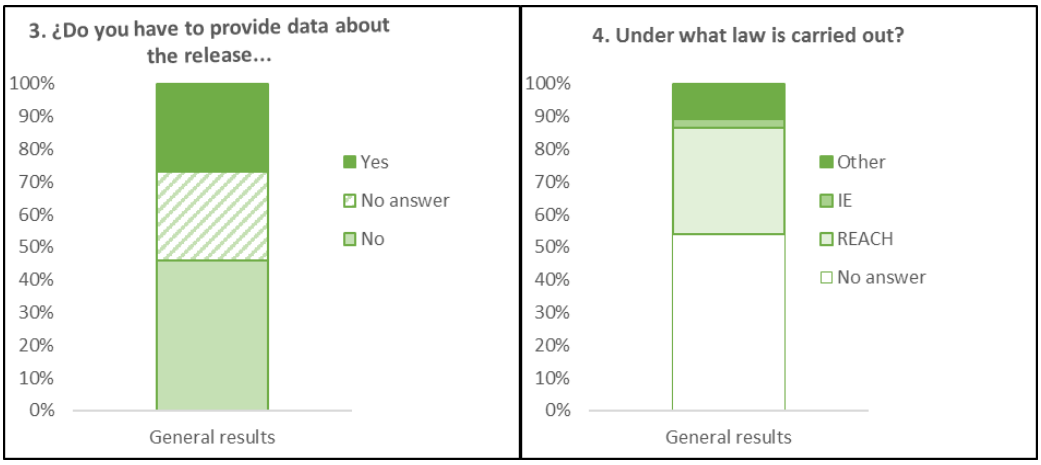


Figure 11: Graphical representation of the responses collected to Q1, Q2, Q3, Q4 during action C1.

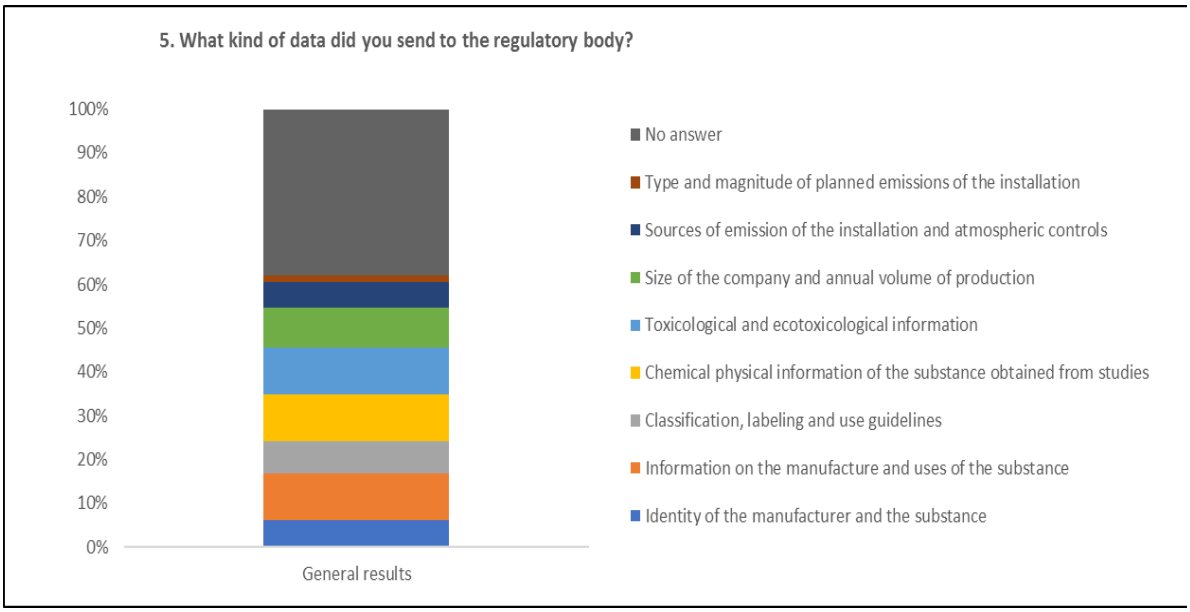


Figure 12: Graphical representation of the responses to Q5 collected during action C1.

5. Current lack of data

Despite increased awareness in public and recent reporting of ENMs in environment, not much information on exposure levels is yet accessible. As we saw in Section 3, specific regulation is still missing. Advances in this sense are basically represented by attempts to adapt and extend to ENMs laws already existing for substances in their bulk form and only in few cases data on concentrations, either directly measured or estimated by means of mathematical models, are requested. Clear specifications are required for nanomaterials and REACH does not provide details concerning information requirements and the chemical safety report for nanoscale forms of substance.

The lack of available data on concentrations of ENMs, both in workplaces and the different environmental compartments, generates subsequent difficulties in compiling risk assessments for worker and consumer exposure. The first three tasks carried out have been fundamental to define the current situation concerning availability, request and use of measured data. This last

task, C1.4, consists in putting together what we learned up to now in the development of action C1, and make an attempt to define and estimate the current lack of data on ENMs concentrations. In this sense, the extensive bibliographic research conducted during Task C1.1 revealed fundamental.

Concerning **occupational exposure**, we adopted a methodology which relies on the quantification of the industrial processes (selected in Task C1.1) covered by the data gathered from bibliographic sources for the different nanomaterials taken into account. We opted for a graphical representation of the situation, in order to transmit visually to the reader a clearer idea of the state of the art. **Table 9** shows in red for which industrial process and nanomaterial published data are lacking. It is clear from the table that the lacking of knowledge prevails for most nanomaterials. Only in the case of titanium dioxide the 73% of the processes are covered by publicly available measures, while the rest of substances do not even reach the 50%.

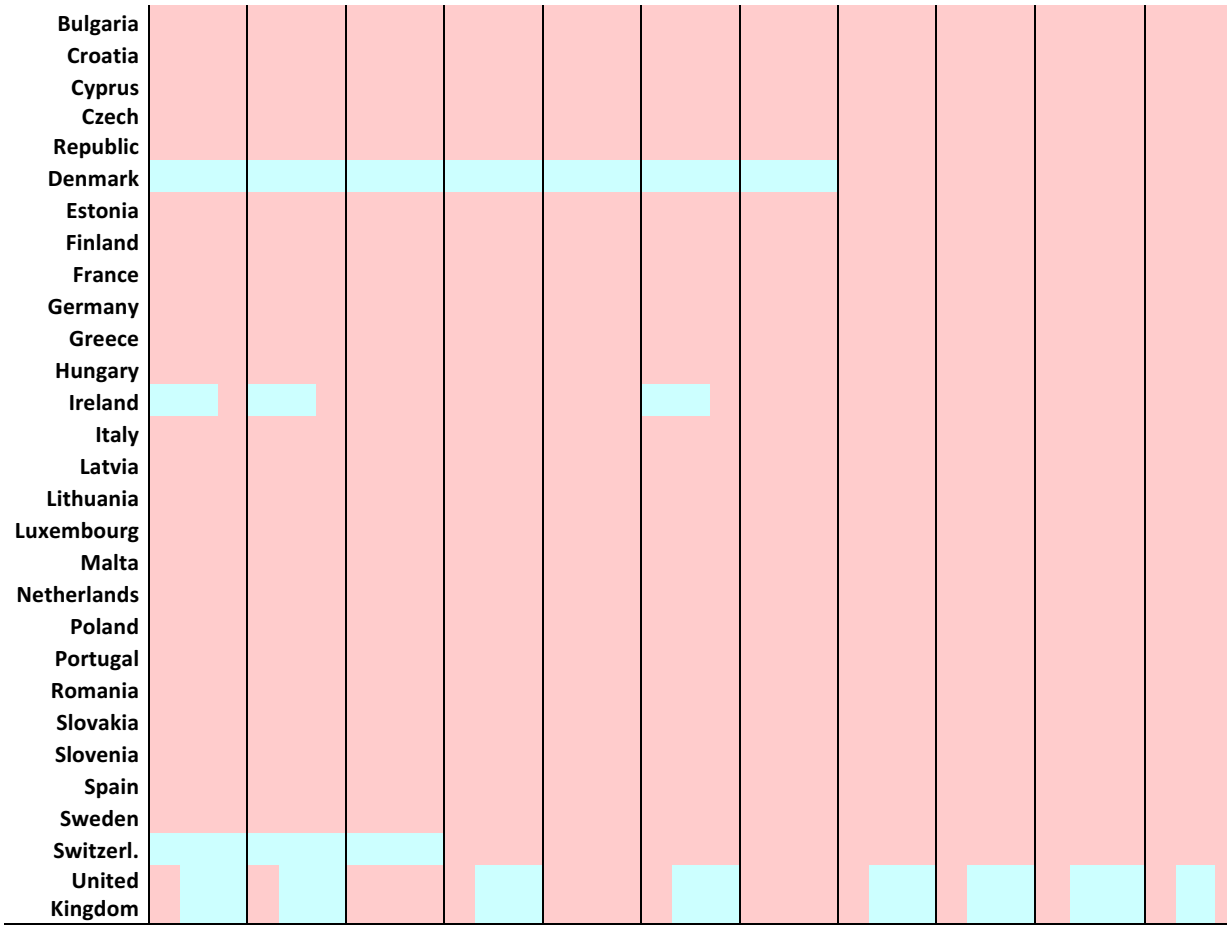
Table 9: Current situation for the lack of ENMs concentrations data in the case of occupational exposure.

	ENM													
Process	**TiO_2**	**Ag**	**AlO_3**	**$CaCO_3$**	**CB**	**CeO_2**	**CNT**	**Cu**	**Fulleneres**	**Graphene**	**Nanoclays**	**SiO_2**	**ZnO**	**ZrO_2**
Cleaning														
Coating														
Extrusion														
Heating														
Pyrolisis														
Spraying														
Production														
Weighing, mixing, transferring														
Machining (sawing, grinding)														
Sonication														
Packing														
	73%	**36%**	**9%**	**9%**	**18%**	**9%**	**36%**	**9%**	**9%**	**27%**	**9%**	**45%**	**36%**	**18%**

When dealing with environmental release, the situation is even worse. The data available are absolutely scarce, due both to the lack of standardized methods and experimental challenges, making risk assessment through the ENMs life cycle very difficult. The data collected from bibliography during Task C1.1 perfectly reflect this condition. In **Table 10**, where the same graphical methodology of Table 9 is used, the lack of data on environmental concentrations is represented, differentiating by country, by substance and also considering the three fundamental environmental compartments (A=Air, W=Water and S=Soil). The table shows that, currently, public data on environmental release only exist for four European countries (Denmark, Ireland, Switzerland and United Kingdom). The countries and environmental compartments covered by existing data constitute a good parameter for a sound definition of the lack of environmental data.

Table 10: Current situation for the lack of ENMs concentrations data in the case of the three environmental compartments (A=Air, W=Water and S=Soil) for different countries.

	Environmental concentration data																																						
	TiO_2			**Ag**			**CNT**			**ZnO**			**$CuCO_3$**			**CeO_2**			**CB**			**Gold**			**Al_2O_3**			**Fullerenes**			**SiO_2**		
Countries	A	W	S	A	W	S	A	W	S	A	W	S	A	W	S	A	W	S	A	W	S	A	W	S	A	W	S	A	W	S	A	W	S	A	W	S
Austria																																				
Belgium																																				

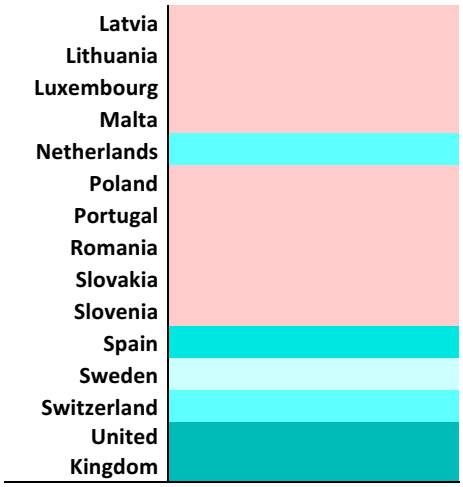


When we move to urban environments, the situation slightly improves. **Table 11** shows the availability of public data on ENMs concentration in urban environments for the different European countries. Data exist for the 47% of the countries. The differences in the shade of blue (labelled from 1 to 5) are introduced to quantify this availability. To darker blue corresponds a larger amount of data, to be intended as measurement campaigns conducted in more cities.

Table 11: Current situation for the lack of ENMs concentrations data for urban environments.

Countries	Urban concentration data
Austria	
Belgium	
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
Estonia	
Finland	
France	
Germany	
Greece	
Hungary	
Ireland	
Italy	

1
2
3
4
5



6. Conclusions

The objective of action C1 was to obtain a comprehensive picture of the current situation regarding environmental/exposure monitoring data, taking into account four different aspects of the issue: their availability in Task C1.1, their demand under different regulations in Task C1.2, their current use in Task C1.3 and the definition of their lack in the regulatory context in Task C1.4. In the following paragraphs, we summarize and comment the results obtained.

From the analysis of bibliographic sources done for the first task, we could gather and quantify the available data on concentration of ENMs, distinguishing between occupational exposure, environmental release and urban locations. The data have been organized following different criteria, like the industrial process covered and the country where the measure was taken in the case of environmental and urban monitoring. This arrangement of the available data was the first step for constructing a solid definition of the lack of data required by Task C1.4, since it allowed us to establish the different criteria it could be built on. We found that the number of the processes covered by the data and the different substances involved, are two good parameters to define the lack of data in the case of occupational exposure. In the case of the environment, we selected as criteria the number of countries covered by the measures, the substance and the different compartment, while in the case of urban environment we considered the countries covered and the amount of data available for each country, since the experimental methodology does not allow to differentiate between different substances.

We found out, as expected, that data on the concentration of ENMs are extremely scarce in the three cases. We ascribe this reality not only to the objective experimental and methodological difficulties that occur when dealing with particles at the nano scale, but also to the lack of specific regulation and clear specification on the demand of data under the different existing laws and regulations that emerged carrying out Task C1.2.

Beside the few responses we received, this situation is perfectly reflected in the results of the survey we conducted during Task C1.3, where most the respondent declared that they are not required to provide measured data on concentration of nanomaterials to the competent authority. However, we are conscious that in order to have a more realistic depiction of reality, more responses are needed and the plan is to keep collecting stakeholders' feedbacks on this fundamental issue during the entire duration of the project.

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NanoMonitor Project is partially funded by the European Commission Life+ with grant agreement LIFE14 ENV/ES/000662