

Methodologies

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1 Introduction

This paper outlines the main methodologies used in the NanoData project.

The data were in large part identified using keywords to search existing databases (e.g. for publications and patents) and to select projects (from eCorda) and products (e.g. from product databases). The report explains how the keywords were identified and what quality control measures were put in place.

It should be noted that, as of December 2015, five sectors were included in the work – energy, health, ICT, photonics and manufacturing. Three sectors are being added in 2016 – construction, environment and transport. Thus, at no point will the data be comprehensive across all of nanotechnology. They are, instead, representative of the sectors selected within the context of the overall project for the European Commission.

The outline of this report is as follows:

- Introduction;
- Development of keywords;
- Methodology by task and sector: publications, projects, patents and products;
- Methodology for additional information: markets, wider economic data, environmental health and safety, regulation and standards; and
- Concluding remarks.

2 Development of keywords

The keywords were identified from known data sources, web searches and expert input. They were validated through discussions with JIIP partners¹ (where they had expertise and experience in the area concerned) and other experts. Following that validation process, the keywords were also tested by one or both of the following methods:

- The word 'nano' and the keywords were used to select the FP projects relevant to the sector (and sub-sectors if appropriate). The projects identified were checked manually for false positives. False negatives were also identified (projects that were expected to be selected that were not). The keywords were refined to optimise the number of projects correctly selected.
- The keywords were used to select publications. The lists of publications were checked, in part manually and in part semi-automatically using the CWTS VOSViewer bibliometric mapping tool (<u>http://www.vosviewer.com/Home</u>). Using the tool, it was possible to see how terms group together in publication space (by their proximity on a VOSViewer map) and how often they occur (by their size on the VOSViewer map). Thus, it was possible to determine which terms would be the most significant in the sector and also which terms would be likely to cause false positives. For example, in the partial map for nanotechnology and health below (bottom left corner) it can be seen that a very important term is 'scaffold', and related terms are about tissue and bone engineering. Moving further to the right, the related term 'biocompatibility' is seen and nearby the significant and related but more generic terms 'surface', 'morphology' and 'synthesis'.

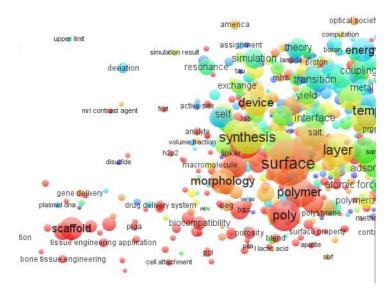


Figure 2-1: Partial VOSViewer map for nanotechnology and health

Additional terms could also be identified for inclusion in the keyword list.

It should be noted that, where the use of a keyword could lead to false results, the keyword

¹ Partners of the Joint Institute for Innovation Policy for this project i.e. CWTS, Frost & Sullivan, Joanneum Research, Oakdene Hollins, the Nanotechnology Industries Association, Tecnalia and TNO.

was omitted. This inevitably leads to some data of relevance being omitted from the resource base of the project, the alternative being the inclusion of much irrelevant information. For example, some words (e.g. photodetector, laser, photolithography) were omitted from the keywords for photonics as they have much wider applications that photonics alone.

In the searches, keywords were truncated to maximise the possible results. For example, in energy, "thermoelectric*" could identify data related to "thermoelectric", "thermoelectrics", "thermoelectrical" and "thermoelectricity", the * indicating the truncation.

Where possible, both British and American spellings were included (e.g. tumour and tumor) as were alternative spellings (e.g. orthopaedic and orthopedic).

3 Publications

Identification of publications relied on analysis of the data in the database at CWTS (the Centre for Science and Technology Studies, Leiden University, the Netherlands), data that is based on that in the Web of Science².

The CWTS database is organised and structured such that it allows (dynamic) field delineation and the collection of relevant publications. Hence it was possible to identify nanoscience and nanotechnology (NST) publications and, within those, to identify publications relevant to the sectors. More specifically, publications were sought within the NST group using the keywords. In addition, using the tools available at CWTS, related publications could be identified and included in the output.

Data available from the resource at CWTS included the journals in which the publications are found, the date of publication and the doi (digital object identifier). For licensing reasons, some of the data in the database at Leiden can be accessed by external parties only in aggregate form. For example, personal details of individual researchers cannot be accessed (e.g. address, email, phone number).

The report uses ISO 2-digit codes for countries. See http://www.iso.org/iso/country_codes

² <u>http://thomsonreuters.com/en/products-services/scholarly-scientific-research/scholarly-search-and-discovery/web-of-science.html</u>

4 Framework Programme Projects

The Framework Programme (FP) project details were provided by the European Commission from the eCorda database for FP6 and FP7. Abstracts for the FP6 projects were provided separately as these were not in the original database received. The total number of FP projects in eCorda database is 35,365 of which 25,238 are FP7 projects and 10,027 FP6 projects. These projects involved 210,177 participations by researchers of which 76,562 are in FP6 and 133,615 in FP7.

The table below presents an overview of the data for FP6 and FP7 according to the variables used in the NanoData analysis. It also identified the number of missing values per variable. It shows that the eCorda database is a nearly complete source of FP6 and FP7 project data and participant data with only relatively few data missing (between 2.4% and 0% of the total for FP6 and FP7 depending on the variable).

Table 4-1: Number of actual observations and missing values for each of the eCorda variables used for the NanoData analysis.

	Number of observations						
	FP6 FP7 Total			Total			
Variable	Actual	Missing	Actual	Missing	Actual	Missing	% Missing
Project ID	10,027	0	25,238	0	35,265	0	0.0%
Start date	9,966	61	24,906	332	34,872	393	1.1%
End date	9,965	62	24,906	332	34,871	394	1.1%
Duration	10,027	0	25,238	0	35,265	0	0.0%
Number of partners	10,027	0	25,238	0	35,265	0	0.0%
Specific Programme	10,027	0	25,238	0	35,265	0	0.0%
Sub-Programme ³	10,027	0	25,238	0	35,265	0	0.0%
Call	9,989	38	25,238	0	35,227	38	0.1%
Instrument	1,0027	0	25,238	0	35,265	0	0.0%
EC contribution	10,027	0	25,238	0	35,265	0	0.0%
Project total cost	9,771	256	25,238	0	35,009	256	0.7%
Project ID	76,562	0	133,615	0	210,177	0	0.0%
Participant ID	76,550	12	133,615	0	210,165	12	0.0%
Participant role	76,562	0	133,615	0	210,177	0	0.0%
Participant legal name	76,561	1	133,615	0	210,176	1	0.0%

³ In FP6 these were called Priorities and in FP7 Work Programmes.

			Number of	fobservatior	าร		
Participant country⁴	76,562	0	133,615	0	210,177	0	0.0%
Participant region	76,562	0	133,615	0	210,177	0	0.0%
Participant organisation type	74,271	2,291	133,615	0	207,886	2,291	1.1%
EC contribution per participant	71,748	4,814	133,569	46	205,317	4,860	2.4%
Project cost per participant	72,960	3,602	133,575	40	206,535	3,642	1.8%

In the eCorda database, the EC contribution per project shows some small differences between the data presented by project (project database) and the data presented by participant (participant database). The table below illustrates the differences, both in millions of euros and as shares of the EC contribution. It can be seen that the difference in EC contribution between the project and participant data is almost zero in FP7 and small in FP6. However, the differences can become significant when the data is aggregated.

Table 4-2: Number of projects and EC contribution for the project data and participant data in eCorda

	Number of projects		EC contribu	tion (MEUR)	Difference (Project	Difference
	Project Data	Participant Data	Project Data	Participant Data	 Participant) (MEUR) 	%
FP						
FP6	10,027	10,027	16,692.320	16,653.860	38.460	0.23%
FP7	25,238	25,238	44,917.330	44,917.200	0.130	0.00%
Total	35,265	35,265	61,609.650	61,571.060	38.600	0.06%
NT						
NT-FP6	908	908	1,702.740	1,695.500	7.250	0.43%
NT-FP7	2,636	2,636	4,660.840	4,660.750	0.090	0.00%
Total	3,544	3,544	6,363.580	6,356.250	7.340	0.12%

4.1 Classification of projects

4.1.1 Classification of nanotechnology projects

In order to identify the baseline set of nanotechnology-related projects for the NanoData work, a search was made for all FP projects that contained 'nano'⁵ in the title or abstract of the

⁴ The report uses ISO 2-digit codes for countries. See <u>http://www.iso.org/iso/country_codes</u>

⁵ The term "nano" could appear as a part of a word (e.g. nanotechnology, nanoscience, nanomaterial, nanoscale), as a part of compound word separated with hyphen (e.g. nano-science) or as an independent word "nano".

project. 3,544 projects were selected in this way⁶, of which 74% were FP7 projects and 26% were FP6 projects. Comparing the distribution of projects between FP6 and FP7 for nanotechnology and for the two FPs overall, it is found that the distributions are very similar the latter being 72% in FP7 and 28% in FP6. Nanotechnology projects make up 10% of Framework Programme projects, the share increasing slightly from FP6 (9.1%) to FP7 (10.4%).

The table below shows the distribution of total FP projects and of nanotechnology projects.

		Total	FP7	FP6
FP total	Number of FP projects	35,265	25,238	10,027
	Share of FP (total)	100%	71.6%	28.4%
Nanotechnology	Number of FP projects	3,544	2,636	908
	Share of FP	100%	74.4%	25.6%
Share of nanotechnology of total FP		10.0%	10.4%	9.1%

Table 4-3: Number and share of nanotechnology projects in FP6 and FP7

4.1.2 Classification of projects by sector and sub-sector

The 3,544 projects relevant to nanotechnology were subjected to a search using the sector keywords to identify projects relevant to each sector. This search was undertaken using the keywords identified for each sector. The project details for the selected projects were reviewed manually, where possible, as a further check of the quality of the outputs of the keyword search process.

For example, in 2015, using the method described above, 944 projects were categorised as being related to nanotechnology and health, approximately 27% of total nanotechnology projects. Using the keywords identified for each of the five health sub-sectors⁷, a further classification could be made. In addition, nanotechnology projects relevant to health but not specifically to any of the five sub-sectors were categorised as Other. In this way, the breakdown of health nanotechnology projects was found to be: cancer 26% (CT); infectious diseases 7.8% (ID); cardiovascular diseases 5.2% (CV); neurodegenerative diseases 4.6% (ND); and diabetes (2.2%) (DB) with Other being 62% (OTH).

Where projects were classified as belonging to more than one sub-sector, a proportion of each such project was allocated to the sub-sector concerned. Thus a project relevant to cardiovascular disease and cancer would be allocated 50% to cardiovascular disease and 50% to cancer. The aim was to ensure an accurate analysis of the FP project data and to minimise double counting. The table that follows shows the number of project overlaps and the distributions of fractions of projects for the health sub-sectors.

⁶ Unlike the other sectors considered by the project (HT, EN, PH, MF), for ICT additional projects were identified by use of keywords such as graphene. These were judged to be too important in ICT to be omitted. This did, however, result in the total number of nanotechnology projects being different for ICT (4,143) and the other sectors (3,544).

⁷ Cancer, cardiovascular disease, diabetes, infectious diseases and neurodegenerative diseases.

	Total	СТ	CV	ID	NE	DB	Other
Projects without overlaps	883	196	23	48	24	11	581
Projects with overl	aps: fracti	ons as alloo	ated				
CT & ID	17	8.5		8.5			
CT & CV	12	6	6				
CT & ND	9	4.5			4.5		
CV & ID	5		2.5	2.5			
CV & ND	4		2		2		
CT & DB	4	2				2	
CV & DB	3		1.5			1.5	
ND & DB	2				1	1	
CT, ID & ND	1	0.33		0.33	0.33		
CT, ND & DB	1	0.33			0.33	0.33	
CT, CV & ID	1	0.33	0.33	0.33			
CT, CV, ID & ND	1	0.25	0.25	0.25	0.25		
ID & ND	1			0.5	0.5		
Sum of fractions	61	22	13	12	9	5	0
Total nanotechnology and health	944	218	36	60	33	16	581

Table 4-4: Distribution of projects with overlaps across health sub-sectors

4.2 Harmonisation of data across FP6 and FP7

In order to have harmonised variables across both Framework Programmes, some names and coding of variables were required. These included the following:

 Harmonising the participant types. The categories used in this report are presented in the table below. In the tables of top performers, if the same organisation appeared in FP6 and FP7, the FP7 code was used.

 Table 4-5: Harmonising participant type codes.

Codes used	Description	FP6 Code	FP7 Code
HES	Higher or secondary education establishment	HES	HES
REC	Research organisations	REC	REC
PRC	Private commercial (excluding SMEs)	IND	PRC
SME	Small and medium-sized enterprises	SME	SME
ОТН	Other including public bodies excluding research and education	ОТН	OTH, PUB

Further information on this methodology is available if required.

ii) Introducing a classification of instruments in order to allow enhanced comparison between the varieties of instruments. The categorisation follows that of Arnold et. al (2012)⁸.

Action	Instrument	FP
Research actions	ERC Grants	FP7
Collaborative RTD actions	Integrated Projects	FP6
RTD actions	Specific Targeted Research Projects	FP6
	Large-scale Integrating Project	FP7
	Small or medium-scale focused research project	FP7
	Integrating Activities / e-Infrastructures	FP7
	Collaborative project (generic)	FP7
Actions for RTD	Specific Actions to Promote Research Infrastructures	FP6
knowledge transfer	Marie Curie Actions	FP6
	Coordination Actions	FP6
	Network of Excellence	FP6
	Coordinating Action	FP7
	Marie Curie Actions	FP7
	Research Infrastructure	FP7
	Collaborative project dedicated to international cooperation partner countries (SICA)	FP7
Actions for	Co-operative Research Projects	FP6
adoption and innovation	Collective Research Projects	FP6
	Joint Technology Initiatives	FP7
	Research for SMEs	FP7
Actions to	Specific Support Actions	FP6
support policymaking	Supporting Action	FP7

Table 4-6: Classification of instruments

iii) Participant organisations identifiers

For the FP6 and FP7 participants the following organisation identifiers were used:

⁸ In their work Arnold et. al. (2012) Understanding the Long Term Impact of the Framework Programme classifies the instruments of FP4, FP5 and FP6 into four categories that are used as guidance for our classification. For FP7 the classification is done by authors of this report.

- FP7: CD_ORG_ID and
- FP6: Participant Identifying Code-PIC.

If these were not available, the programme participant identifiers were used. In order to improve the comparability of the FP6 and FP7 participant identifiers, some manual matching based on organisation legal name and address data was conducted for the NT participant sample. As a result, 5,945 unique nanotechnology participants were identified.

4.3 Treatment of decimals

As a general rule, the data in the tables and figures are produced by utilising the method of first summing the unrounded figures and then rounding the sum. Due to this process, some totals may not correspond with the sum of the separate figures (generally presented as limited to one decimal).

4.4 Key terminology and abbreviations used

Table 4-7: FP6 funding instrument types

Code	FP6 Type of instrument
STREP	Specific Targeted Research Projects
CA	Coordination Actions
SSA	Specific Support Actions
П	Specific Actions to Promote Research Infrastructures
IP	Integrated Projects
NOE	Networks of Excellence
MCA	Marie Curie Actions
CRAFT	Co-operative Research Projects
CLR	Collective Research Projects
13	Specific Actions to Promote Research Infrastructures

Table 4-8: FP7 funding instrument types

Code	FP7 Type of instrument
СР	Collaborative project
ERC	Support for frontier research (European Research Council)
MC	Support for training and career development of researchers (Marie Curie)
JTI/169	Activities under Article 169 or 171 European Treaty, Joint Technology
	Initiatives, Public Private Partnerships
CSA	Coordination and support action
BSG	Research for the benefit of specific groups
NOE	Network of Excellence

Table 4-9: Organisation types

Code	Description
HES	Higher or secondary education est.
РСО	Private companies excluding SMEs
REC	Research organisations
SME	Small and medium-sized enterprises
OTH	Other (incl. public bodies and bodies with unknown organisation types)

Table 4-	-10 [.] Cour	ntry cod	es FU	28+⁹
I abic 4	-10. Coul	iti y cou	C3 LU	207 .

NUTS0	Country	NUTS0	Country	
AT	Austria	LU	Luxembourg	
BE	Belgium	LV	Latvia	
BG	Bulgaria	MT	Malta	
CY	Cyprus	NL	Netherlands	
CZ	Czech Republic	PL	Poland	
DE	Germany	PT	Portugal	
DK	Denmark	RO	Romania	
EE	Estonia	SE	Sweden	
ES	Spain	SI	Slovenia	
FI	Finland	SK	Slovakia	
FR	France	UK ¹⁰	United Kingdom	
EL ¹¹	Greece	СН	Switzerland	
HU	Hungary	IL	Israel	
HR	Croatia	IS	Iceland	
IE	Ireland	TR	Turkey	
IT	Italy	NO	Norway	
LT	Lithuania	ZK	Macedonia	

⁹ Data was also analysed from countries outside of the EU28 namely Iceland (IS), Israel (IL), Norway (NO), Switzerland (CH) and Turkey (TR). ¹⁰ GB is also used

¹¹ GR is also used

5 Patents

The patents analysed were collected from the database PATSTAT, version Spring 2014. That database includes patents from over 30 patent offices e.g. the European Patent Office, the US Patent Office and the Japanese Patent Office.

All patent offices worldwide tag nanotechnology-related patent applications using a special symbol of the International Patent Classification (IPC), namely B82Y. This special symbol is also part of the CPC (Co-operative Patent Classification). The core dataset of nano-related patents were selected using this special symbol (B82Y) from both the IPC and the CPC classifications.

All patent applications at the USPTO, the EPO and PCT (WIPO) classified as B82Y were identified in PATSTAT as well as the (simple) patent family to which they belong. From all these patent families, only patent applications at the USPTO, the EPO and PCT (WIPO) were collected. Such use of multiple patent offices helps to diminish the bias that might be caused by the so called 'home advantage' effect, i.e. the propensity of nationals to file the first patent application in their own country. By analysing across these three patent authorities a less biased overview of nanotechnology patents worldwide can be obtained.

As the patent information is being collected from more than one patent authority, and given that the same invention might be protected in more than one of these patents authorities, the (simple) patent families are used to avoid multiple counting of the same invention.

The identification of patents by sector from amongst the nanotechnology patents was based in most cases on the combination of two strategies. First, all patents including in their title and/or abstract at least one relevant keywords for a particular sector were retrieved. Second, to ensure that the patents retrieved in the first step are truly related to the sector, a number of representative IPC symbols of the sector were selected from PATSTAT¹². For example, for the nanotechnology patents related to the health sector, the IPC symbols related to 'Pharmaceuticals' and 'Medical technology' were used. However, it was not possible to undertake this second step for all sectors as for some (e.g. manufacturing) there were no appropriate IPC symbols.

Organisations and/or individuals are listed in patent applications, these being applicants and/or inventors. This information is used in the identification of companies, universities and other research organisations active in patenting. The year of reference used is the year when the oldest priority of each patent family was applied (the closest date to the invention). The report uses ISO 2-digit codes¹³ for countries.

¹² PATSTAT also contains a table mapping 44 industrial sectors and the IPC classification. The linkage between technology areas and industrial sector is described in Schmoch et al (2003), "Linking Technology

Areas to Industrial Sectors", final report to the European Commission, DG Research. ¹³ <u>http://www.iso.org/iso/country_codes</u>

6 Products

Products were identified primarily through keyword, sector and sub-sector searches of reports and databases. This search strategy was based on a triangulation approach making use of complementing perspectives. For all perspectives the NanoData team made use of the sector specific lists of key words.

The first step was to use peer-reviewed and grey literature on products in the different sectors¹⁴ as well as existing market reports¹⁵. The market reports were used to identify where nanotechnology is being applied already in products as there are many reports that appear to identify products but no product is for sale at a commercial level, being at the research stage or for very limited supply e.g. to the research community or for test purposes. These investigations were then complemented by querying web-based databases on nanotechnology products such as AZONANO¹⁶, Nanowerk¹⁷, the consumer products inventory of the Project on Emerging Nanotechnologies¹⁸, the product database of understandingnano.com¹⁹, the Nanoinformationsportal of the Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH²⁰, the Danish Inventory of Nanoproducts²¹ and the nanowatch.de database²². Further sector-specific databases, such as the German database for medical practitioners and the database on European public assessment reports of the European Medicines Agency²³, were used for the identification and classification of nanotechnology related products in health, for example.

By querying databases on existing innovation policy projects, initiatives and industry platforms such as NANORA²⁴, the Nano-Map of the German Federal Ministry of Research²⁵, the database on photonic companies compiled by EPIC, the members directory of SEMI²⁶, and the Nano-Bio Manufacturing Consortium (USA)²⁷, additional enterprises active in nanotechnology sectors were identified.

A third perspective on products was developed by gathering additional information about the products from company websites identified in previous work, commercial databases and open sources of information on the web. The information was verified through additional searches (e.g. of product data sheets and company websites).

¹⁴ E.g. Nanomedicine: Nanotechnology, Biology, and Medicine 9 (2013) 1–14, Hessen Nanotech (2008) Applications of Nanotechnologies in the Energy Sector.

¹⁵ See BCC Research <u>www.bbcresearch.com</u>

¹⁶ http://www.azonano.com/

¹⁷ http://www.nanowerk.com/

¹⁸ http://www.nanotechproject.org/cpi/

¹⁹ http://www.understandingnano.com/nanotechnology-product-suppliers.html

²⁰ http://nanoinformation.at/produkte.html

²¹ http://nanodb.dk/

²² http://www.bund.net/nc/themen_und_projekte/nanotechnologie/nanoproduktdatenbank/

²³ http://www.ema.europa.eu/

²⁴ http://www.nanora.eu/

²⁵ http://www.werkstofftechnologien.de/en/

²⁶ http://www.semi.org/en/Membership/MemberDirectory/

²⁷ http://www.nbmc.org/members-only/

The information in the database was extensively verified. Where, for example, it was found that a product was identified but not verified, searches were made of sources including reports and company websites to check the information. Contact was also made, in some cases, directly with the company in order to ratify the existence on the market of the product. While some other databases actually state the level of known accuracy of their information (e.g. the entries in the Woodrow Wilson database are classified using a system that has categories from level 1 (extensively verified claim) to level 5 (not advertised by manufacturer – claims made only by third party)) others are not specific.

In NanoData, the aim is only to include products that can be verified.

7 Other information

Several types of information are provided on the NanoData site as fixed text where data is limited or one-off. These include information on markets and wider economic data, as well as reports on environmental health and safety and information about regulation and standards.

Markets

The market data is based on available sources of information and sources of Frost & Sullivan and BCC Research, who gather their information through discussions with practitioners (e.g. company representatives) and open sources (e.g. commercial reports, web sites). The aim was to track, evaluate and measure the activities of major industry participants in the nanotechnology arena, looking at markets and usage of nanotechnology. The activities included the definition and specification of nano-materials and nano-enabled products, identification of current and upcoming products and applications, accumulating qualitative and quantitative data, identification and mapping of EU participants and last but not the least, identification and analysis of target markets.

A wide set of definitions, categorisations, data collection and forecasting methods were available. Data gathering was driven by experienced analysts and based on a data-rich portfolio of previous EU and OECD projects as well as on internal Frost & Sullivan databases and consortium members, and public database. European Patent Office²⁸, PRODCOM²⁹ and patentlens³⁰ databases could be used to provide in-depth information about a particular technology and to identify the key industry participants dominating the sector. Analysis of key value chains was undertaken and corroborated with other work-streams. The information thus acquired would be verified with the help of an array of primary interviews with leading technology researchers, industry experts and other active stakeholders.

The range of primary and secondary research processes would be followed by the application of innovation diffusion tools in order to forecast probable market scenario of the future. This would also include estimating the shape of the diffusion curve and prediction of market development of nano-enabled products.

Wider Economic Data

External information sources such as Eurostat, OECD and WHO data sources were used to put the nanotechnology data obtained in the project into context.

For example:

- A brief overview of the energy industry was based on Eurostat data.
- The health industry overview was based on Eurostat data supplemented by reports from industry organisations (both technical (e.g. the industry association for European pharmaceutical enterprises) and financial (e.g. the European Private Equity & Venture Capital Association))

²⁸ <u>https://www.epo.org/searching.html</u>

²⁹ <u>http://ec.europa.eu/eurostat/web/prodcom</u>

³⁰ <u>https://www.lens.org/lens/search?n=10&q=nanotechnology&p=0</u>

While reports on industry as a whole were available, there were found to be very few reliable reports on nanotechnology and industry. Nanotechnology databases were also explored (e.g. those of Nanowerk and Nanora).

Environmental health and safety

For the sectors in which materials were the main focus, the tool used for the environmental health and safety evaluation was the "Stoffenmanager Nano" application³¹. In summary, Stoffenmanager Nano is a risk-banding tool developed for employers and employees to prioritise health risks occurring as a result of respiratory exposure to nanoparticles for a broad range of worker scenarios. In the absence of a comparable tool for consumer exposure, it was also used for this type of exposure. Stoffenmanager Nano combines the available hazard information of a substance with a qualitative estimate of potential for inhalation exposure. Stoffenmanager Nano does not consider dermal and oral routes of exposure.

In Stoffenmanager Nano, the available hazard information is used to assign specific nanoparticles to one of five hazard bands, labelled A to E (A= low hazard, E= highest hazard). Likewise, exposure bands are labelled 1-4 (1=low exposure, 4= highest exposure).

The hazard and exposure bands are combined to yield so called priority bands ranging from low priority (=4) to high priority (=1). A high priority implies that it is urgent to apply exposure control measures or to assess the risks more precisely, and a low priority implies that it is not very urgent to apply exposure control measures or to establish the risk involved with more precision.

Regulation and standards

International, European, national and regional data sources for regulation and standards include:

European documents:

- Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) - 1907/2006(EC);
- Regulation on Medical Devices 2012/0266(COD); and
- European Commission Recommendation on the Definition of a Nanomaterial,

as well as sectoral documents such as

- Nanomaterials in the Healthcare Sector: Occupational Risks & Prevention E-fact 73; and
- Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Device.

National documents:

- Decree on the annual declaration on substances at nano-scale 2012-232 (France);
- Royal Decree regarding the Placement on the Market of Substances manufactured at the Nano-scale (Belgium); and

³¹ Van Duuren-Stuurman, B., Vink, S., Verbist, K.J.M., Heussen, H.G.A., Brouwer, D., Kroese, D.E.D., Van Niftrik, M.F.J., Tielemans, E., Fransman, W., 2012. Stoffenmanager Nano version 1.0: a web-based tool for risk prioritization of airborne manufactured nano objects. Ann. Occup. Hyg. 56, 525-541.

• Order on a Register of Mixtures and Articles that contain Nanomaterials as well as the Requirement for Manufacturers and Importers to report to the Register – BEK nr 644 (Denmark).

8 Concluding remarks

This document outlines the main methods for the selection of data for analysis, some data sources, the aggregation of data classes in order to enable analysis (mainly for the FP projects) and the ways in which data was analysed. References are made to some of the main quality control issues.

This document is not exhaustive and does not discuss the methodology for data acquisition, cleaning and use in the NanoData database.

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