#32

COMPLETE

Collector: Nano Consult - Non-Industry (Web Link)
Started:
Last Modified:
Time Spent:
IP Address:

PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Name of organisation* (if applicable):	National Institute of Public Health and the Environment (RIVM)
Town/City:	Bilthoven
Country*:	The Netherlands
E-mail address:	
Q2: Please indicate if you are responding to this questionnaire on behalf of/as:	Other (please specify) The National Institute for Public Health and the Environment (RIVM) is a health and safety institute owned by the government that provides advice to assist government authorities at all levels to protect the quality of public health and the environment. RIVM's independent status is established by Act of Parliament. Clients approach RIVM with clearly formulated research questions. They have no further influence over the form or findings of the research itself. RIVM strives to be a reliable partner to the Dutch government. Its advice on policy-related matters is always carefully considered and balanced.
Q3: Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution:	My contribution may be published under the name indicated
Q4: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted

PAGE 3: Section III – Problem definition and objectives

Q5: Please rate the importance of the following objectives on a scale between 1 (not important at all) and 5 (very important).

a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials	5
b) Provide consumers with relevant information on products containing nanomaterials on the market	5
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	3
d) Ensure consumer trust in products containing nanomaterials	3
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	5
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	4
g) Protect confidential business information	3
Please provide additional comments	On statement b and d: providing transparency to the consumer (by providing relevant information) is important. Whether this transparency leads to ensuring consumer trust (d) is highly dependent on what the consumer thinks of the information provided. Note: this question has been interpreted as the general importance of the described topics, not specifically in relation to a database

Q6: To what degree (from 1 - not at all to 5 - fully) does the current legislative framework (including the REACH and CLP Regulations and product-specific legislation) and the currently available databases (including the JRC web platform, see http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials) meet the following objectives?

a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials	2
b) Provide consumers with relevant information on products containing nanomaterials on the market	2
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	3
d) Ensure consumer trust in products containing nanomaterials	2
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	2
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	5
g) Protect confidential business information	5
Please provide additonal comments	The RIVM opinion regarding the feasibility of existing legislation for regulating nanomaterials is described in a recent published report of Bleeker et al. (2013) See also: E.A.J. Bleeker | D. Theodori | S.W.P. Wijnhoven, 2013. Exploring Building Blocks for Amending EU Regulation of Nanomaterials. RIVM report 601353003/2013 On statement b: there is only some legislation available (biocides, cosmetics, food) ensuring that information on nano-ingredients is available for consumers. However, the term nano as well as the nano-definition is meaningless for a large group of consumers. Furthermore, in most legislation, obligation to label nano-information is absent. On statement c: Companies are becoming hesitating in the use of NM for their products, because of large ambiguities around the nano-definition, measurement methods and consequences of this for safety research. On the other hand, when they are already on the market with a nano-enabled product, they are suddenly confronted with discussion around nano.

Q7: To what extent do you agree with the following statements from 1 (strongly disagree) to 5 (strongly agree):

a) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for an adequate response to health and environmental risks	4
b) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for informed consumer choice	5
c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust	3
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way	5
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	5
Please provide additional comments	On statement c: The group of consumers is a very broad group. For some of them information on content of consumer goods (including nanomaterials) is very important, for others (much) less so. On statement e: Please be aware that if a EU register is established, the harmonisation of the different existing national registers will be very complex as they are all (slightly) different. See also: S.W.P. Wijnhoven et al, 2011. Development of an inventory for consumer products containing nanomaterials. 070307/2010/580587/SER/D3 http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2010/december/Development_of_an_inventory_for_consumer_products_containing_nanomaterials_Final_report?sp=cml2bXE9ZmFsc2U7c2VhcmNoYmFzZT00MzYyMDtyaXZtcT1mYWxzZTs=&pagenr=4363

PAGE 4: Section IV – Health and environmental aspects

Q8: With regard to health and environmental hazards and risks of specific nanomaterials/types of nanomaterials, please tick the relevant boxes:

I am aware of health and/or environmental hazards of specific nanomaterials/types of nanomaterials

,

I am not aware of any classified nanomaterials,

I am aware of DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials

,

I am aware of significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials

,

Please explain your responses (if any, please report the nanomaterials, the health and/or environmental hazards, any relevant classification, any DNELs/PNECs/OELs, any exposure and in which condition):
We are aware of at least indicative (not binding) PNEC and OEL levels for a couple of nanoparticles. Indicative PNECs have been derived within the EU FP7 project Nanofate based on the data generated in the pro-ject (http://www.nanosafetycluster.eu/eu-nanosafety-cluster-projects/seventh-framework-programme-projects/nanofate.html) OELs: until now no binding regulatory limit values have been derived, and are not expected to be derived on the short and medium term. However, for a few nano-substances indicative limit values have been derived (see table below. Private OELs, set by industry, are not always publicly available because of intellectual property rights. Nano-related limit values for occupational exposure Type Value (unit) Source Status amorphous silicon dioxide TRGS 900 Germany: (Greim et al. 1989, TRGS 900 2007 TiO2 (nano) REL 300 ug/m3 NIOSH (US) Recommended CNF/CNT REL 1 Resp. fract. NIOSH (US, 2013) Recommended TiO2 1200 ug/m3 NEDO private CNT DNEL 0,7-20 ug/m3 ENRHES (EC2010) MWCNT [bay-tubes] OEL 50 ug/m3 Bayer (Germany) private MWCNT [nanocyl] OEL 2,5 ug/m3 Nanocyl (Belgium) private In the Netherlands, to bridge the period until OELs are available, the Dutch government established provisional reference values for assessing worker risks. See also: S. Dekkers and C. de Heer. Tijdelijke nano-referentiewaarden. RIVM Report 601044001/2010 (in Dutch). http://www.rivm.nl/dsresource?objectid=rivmp:15518&type=org&disposition=inline We are not aware of indicative DNELs

Q9: With regard to the past and current use of nanomaterials (tick the relevant box):

I am aware of health and/or environmental incidents which have occurred

,

Please explain (if any, please report the events and any scientific publication):
The following references are few of the rare publications on health effects after nanoparticle exposure. • Exposure to nanoparticles is related

exposure." "Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma. Song,Y., Li,X., and Du,X. (2009). Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma. Eur Respir J 34, 559–67. doi: 10.1183/09031936.00178308. Epub 2009 Aug 20. Abstract Nano materials generate great benefits as well as new potential risks. Animal studies and in vitro experiments show that nanoparticles can result in lung damage and other toxicity, but no reports on the clinical toxicity in humans due to nanoparticles have yet been made. The present study aimed to examine the relationship between a group of workers' presenting with mysterious symptomatic findings and their nanoparticle exposure. Seven young female workers (aged 18-47 yrs), exposed to nanoparticles for 5-13 months, all with shortness of breath and pleural effusions were admitted to hospital. Immunological tests, examinations of bacteriology, virology and tumour markers, bronchoscopy, internal thoracoscopy and video-assisted thoracic surgery were performed. Surveys of the workplace, clinical observations and examinations of the patients were conducted. Polyacrylate, consisting of nanoparticles, was confirmed in the workplace. Pathological examinations of patients' lung tissue displayed nonspecific pulmonary inflammation, pulmonary fibrosis and foreign-body granulomas of pleura. Using transmission electron microscopy, nanoparticles were observed to lodge in the cytoplasm and caryoplasm of pulmonary epithelial and mesothelial cells, but are also located in the chest fluid. These cases arouse concern that long-term exposure to some nanoparticles without protective measures may be related to serious damage to human lungs. Note: RIVM doubts whether this is the right conclusion since it is not clear what the actual source of the exposure is (nanoparticles, other chemicals or a combination)
• Occupational handling of Nickel nanoparticles- A case report W. Shane Journeay and Rose H. Goldman. American Journal of Industrial Medicine, May 2014, DOI DOI: 10.1002/ajim.22344 Abstract A 26-year-old female chemist formulated polymers and coatings usually using silver ink particles. When she later began working with nickel nanoparticle powder weighed out and handled on a lab bench with no protective measures, she developed throat irritation, nasal congestion, “post nasal drip,” facial flushing, and new skin reactions to her earrings and belt buckle which were temporally related to working with the nanoparticles. Subsequently she was found to have a positive reaction to nickel on the T.R.U.E. patch test, and a normal range FEV1 that increased by 16% post bronchodilator. It was difficult returning her to work even in other parts of the building due to recurrence of symptoms. This incident triggered the company to make plans for better control measures for working with nickel nanoparticles. In conclusion, a worker developed nickel sensitization when working with nanoparticle nickel powder in a setting without any special

	nickel powder in a setting without any special respiratory protection or control measures.
Q10: The establishment of an EU nanomaterial registry (tick the relevant box):	I do not know, If appropriate, please explain further: The uncertainties among the risks are very important here. Any way of registration of products with nanomaterials, either in the value chain or in a publicly available register, is helpful for traceability. Especially, when a nanomaterial appears to be hazardous in a specific form. Furthermore, this will also be relevant for transparency. However, gaining more insight in presence of nanomaterials in products does not necessarily reduce health and/or environmental risks. See also: S.W.P. Wijnhoven and C.N. Noorlander. Opinions in the Netherlands on European registration of consumer products containing nanomaterials. RIVM report 601358/2013 (In Dutch, with executive summary in English). http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2013/september/Opinions_of_Dutch_stakeholders_with_regard_to_registration_of_products_containing_nanomaterials C.N. Noorlander and S.W.P. Wijnhoven. Opinions in the Netherlands on European registration of consumer products containing nanomaterials. Executive summary. http://www.rivm.nl/dsresource?objectid=rivmp:217043&type=org&disposition=inline

PAGE 5: Section V – Consumer trust

Q11: In case information on the presence of nanomaterials in specific products were made available, what impact do you think this would have on consumers? (Please tick all that would apply)	Please explain: The group of consumers is a very broad group. For some of them information on content of consumer goods (including nanomaterials) is very important, for others (much) less so. Answering this question is impossible, because it will depend on a combination of factors like type of consumers and type of product.
Q12: Do you believe that the public availability of information on the presence of nanomaterials in products would be likely to...(choose one of the following answers)	Comments: The group of consumer is a very broad group. For some of them information on content of consumer goods (including nanomaterials) is very important, for others (much) less so. Answering this question is impossible, because for consumers it will also depend on the type of product. Furthermore, the definition of a nanomaterial is crucial in this. The current definition of nano is meaningless for consumers, so putting this on the label of a consumer product does not make sense for many people.

PAGE 6: Section VI - Innovation and competitiveness

Q13: **With regard to innovation, do you believe that information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry would...(choose one of the following answers)**	Comments: Again, difficult to give an answer to this question. Information could help stimulating innovation (companies could learn from each other), but on the other hand it could hamper innovation, because investing in innovation for competitors is not likely. Transparency on both presence of nanomaterials in products and the (un-certainty of) possible risks is a pre-condition for acceptance of (further development of) Nanotechnology and Nanomaterials by the general public. Difficult to say, it could create increased awareness for including safety aspects in early phases of innovation.
Q14: **With regard to competitiveness of EU companies manufacturing nanomaterials or products containing nanomaterials, do you believe that information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry would...(tick all that apply)**	Please explain The answer to this question strongly depends on how a registry is set up, what the costs are to maintain it and who is paying. An EU- registry could also set an example for the rest of the world (maybe comparable to REACH-legislation that is now copied in Asia). Furthermore, another advantage might be that developers of nano-enabled products can get more insight in the kind of products that are already available on the market, learning from each other's experience and information.

PAGE 7: Section VIII – Possible options and exemptions

Q15: **What would be the added value of a notification per use (i.e. for each mixture/article) compared to a notification per substance? – Please consider the usefulness of the information for public authorities, downstream user companies, workers and consumers.**

For all parties mentioned, a registry per use/ product is more useful. To ensure traceability, registration per use and product is probably more effective than per substance, because then the product is the starting point. This ensures that all necessary details on the product and the nano-sized ingredients are well covered in the registration. Also for transparency reasons, the information for the consumer will be more detailed and useful when the nano-enabled product is the starting point.

Q16: **Which actors along the supply chain should be subject to notification requirements? (tick all that apply):**	a) Manufacturers of nanomaterials, b) Importers of nanomaterials, c) Downstream users (e.g. re-formulators, manufacturers of products containing nanomaterials) , d) Distributors to professional users (e.g. wholesalers) , Please explain: It can be assumed that products will not change anymore from wholesalers to retailers. Therefore, notification by retailers is likely to be captured sufficiently by notification by wholesalers.

Q17: **The following should be subject to notification requirements (tick all that apply):**	b) Mixtures containing nanomaterials, c) Articles with intended release of nanomaterials , d) Articles containing nanomaterials without intended release , Please explain: For full transparency and traceability, also the latter option is important. Release is important for potential exposure and risk, but that is another question (not being solved by this registry). So for a complete overview of products with nanomaterials on the market, also products without intended release should be covered.
Q18: **Is there a need to exempt certain types of nanomaterials?**	No, all kinds of nanomaterials should be subject to notification obligations , If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.) For full transparency and traceability, it is essential that all types of nanomaterials are included in a notification. Only from a cost perspective exemptions may be considered, but this should then also be compared with potential benefits in human and environmental health (and other benefits of the registry).

Q19: Is there a need to exempt certain uses of nanomaterials?	No, all uses of nanomaterials should be subject to notification obligations , If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) For full transparency and traceability, it is essential that all uses of nanomaterials are included in a notification. Only from a cost perspective exemptions may be considered, but this should then also compared with potential benefits in hu-man and environmental health (and other benefits of the registry). However, when exemptions have to be made, it is in our opinion most worthwhile to exclude product categories that are already covered by other types of product- specific legislation such as Cosmetics (EU, 2009), Novel Food (EU, 1997) and the Food Im-provement Agent Package (FIAP) in which registration and notification requirements are taken into account. A prerequisite for this is that the different registration systems have to be closely linked to each other so that a complete overview of nano-enabled products is still possible. See also: E.A.J. Bleeker | D. Theodori | S.W.P. Wijnhoven, 2013. Exploring Building Blocks for Amending EU Regulation of Nanomaterials. RIVM report 601353003/2013 http://www.rivm.nl/dsresource?objectid=rivmp:216814&type=org&disposition=inline

PAGE 8: Section IX – Nanomaterials Observatory

Q20: If a Nanomaterials Observatory is established instead of an EU-wide registry, what type of information should be collected? (please tick all that apply)

a) Information from existing notification systems,

b) Information from market studies on nanomaterials and products containing nanomaterials

,

c) Information on the use of nanomaterials across Europe

,

d) Information concerning products containing nanomaterials

,

e) Information on the hazards and risks of nanomaterials

,

f) Other (please explain):
For answering this question, the purpose of a registry should be clearly defined. If the sole aim of such an ob-servatory is transparency and traceability, risk information may be less important, but if the aim also includes ensuring safe use of nanomaterials throughout the supply chain, risk information is essential. The Dutch Risks of Nanotechnology Knowledge and information Centre (KIR nano) aims to provide independent and reliable information for policy makers and the general public on the risks of nanotechnology. KIR nano brings knowledge and research fields together and translates this into policy. Thereby taking a unique position: as an objective party, as an institution that informs and advises, and as pivotal in national and international research. In line with the government policy to encourage nanotechnology KIR nano also has an eye for the social and economic benefits of nanotechnology. KIR nano itself emphatically does not conduct any research. However, to be effective, it does require close collaboration and exchange of information within the field of research, within RIVM as well as on national and international levels. For this reason, the centre continually builds on and maintains a wide national and inter-national network for the performance of its tasks. Within this centre, there has been a lot of experience with discussions around a nanoregister. In the previous answers, reports of studies dealing with this subject are mentioned. One relevant report is the study performed for DG environment, in which the feasibility of a EU register has been investigated. S.W.P. Wijnhoven et al, 2011. Development of an inventory for consumer products containing nanomaterials. 070307/2010/580587/SER/D3 http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2010/december/Development_of_an_inventory_for_consumer_products_containing_nanomaterials_Final_report?sp=cml2bXE9ZmFsc2U7c2VhcmNoYmFzZT00MzYyMDtyaXZtcT1mYWxzZTs=&pagenr=4363

Q21: How should the information in a Nanomaterials Observatory be presented in order to reach the consumers, workers and authorities?

These groups have different expectations/uses for such an observatory. The information should be structured in such a way that these different needs are fulfilled.

PAGE 9: Section X - Potential use and benefits of a nanomaterial registry

Q22: In what ways could the information on nanomaterials from registries be potentially useful (tick all that apply):

a) Risk assessment and/or risk management,

b) Enforcement of worker protection,

c) Promotion of safe use of nanomaterials in products
,

d) Development of strategies to ensure the safe use of nanomaterials

Q23: Please give a justification for your views (presented in the previous question) and describe which data would be necessary to allow the desired use (e.g. would information on substances alone be enough for informed consumer purchase decisions, or would this require information for each concerned product):

When aiming at safe use, information on (potential) hazard has to be linked to information in the nanomaterial registry.
The usefulness for consumers and general education strongly depends on how data are present (e.g. is everything publicly available or only part of the information). For informed consumer purchase decision, product labelling is a preferred communication tool

Q24: What would be the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration?

If the main aim is transparency to consumers and traceability of nanomaterials in the supply chain, product should be the starting point of the registration.
In chemicals legislation, product information (for instance exposure data to product ingredients) is often only available for broad categories of consumer products (if available at all). Getting information on a specific product from the current frameworks of chemical legislation is generally not possible, but essential for clear transparency and traceability. An added value of a European nanomaterial registry is to fill this gap.

Q25: Please provide any other comments that you would like to share regarding transparency measures for nanomaterials on the market.

A discussion in the Netherlands among relevant stakeholders on this subject resulted in the view that for the two identified purposes of the registry also (cheaper) alternatives are available.
1. Product labelling was mentioned as an alternative option for achieving transparency.
2. Dedicated registration of relevant information by industrial partners themselves was seen as an alternative option for ensuring traceability in the supply chain.

Ad1. Transparency for consumers
Mandatory registration or a database of consumer products containing nanomaterials was not seen as the sole option for achieving transparency for consumers. The discussion between stakeholders revealed that product labelling could be seen as an alternative to a register. There is an ongoing discussion about the labelling of products containing nanomaterials. The EU cosmetics regulation and food legislation require products containing nanomaterials to be labelled (name of the ingredient, followed by “nano” in brackets). Comparable labelling requirements for other types of consumer products were seen as a solution by some stakeholders.

Ad2. Traceability in the supply chain
An alternative option to mandatory registration or a database of consumer products containing nanomaterials could be registration by industrial parties. It became clear from the discussion with stakeholders that central registration or a central database is not the ultimate means for ensuring traceability in the supply chain. It is the opinion of the industrial parties involved that all the necessary information is already available in the supply chain. The industrial parties state that it is merely a matter of organizing their information. In this approach, it was concluded that the European Commission should set a framework and rely on timely delivery of information by industry in case of incidents. Consensus between supplier (industry parties) and recipient (government) about the information requested should be achieved at a detailed level in order to secure traceability wherever necessary.

It is at least worthwhile to further investigate these options in the near future.

See also: S.W.P. Wijnhoven and C.N. Noorlander. Opinions in the Netherlands on European registration of consumer products containing nanomaterials. RIVM report 601358/2013 (In Dutch, with executive summary in English).
http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2013/september/Opinions_of_Dutch_stakeholders_with_regard_to_registration_of_products_containing_nanomaterials
C.N. Noorlander and S.W.P. Wijnhoven. Opinions in the Netherlands on European registration of consumer products containing nanomaterials. Executive summary
http://www.rivm.nl/dsresource?objectid=rivmp:217043&type=org&disposition=inline