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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Your name:	Dr Rye Senjen
Name of organisation* (if applicable):	National Toxics Network Australia
Country*:	Australia
E-mail address:	
Q2: Please indicate if you are responding to this questionnaire on behalf of/as:	d) a consumer organisation/trade union/environmental organisation/non-governmental organisation
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)	4
d) Ensure consumer trust in products containing nanomaterials	5
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.	3
g) Protect confidential business information	3
Please provide additional comments	There needs to be a focus on building consumer trust, without it, there will be no place for innovation and development of nanotechnologies in the future. In order to build consumer trust there needs to be greater transparency of nano containing products on the market through labelling and a greater focus on health risks from regulatory authorities.

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)	2
d) Ensure consumer trust in products containing nanomaterials	1
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	1
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	1

g) Protect confidential business information	5
Please provide additonal comments	Several years after the beginning of REACH implementation, and after the first two registration deadlines, information available to public authorities, citizens and consumers is still extremely limited. ECHA's analysis of information provided through REACH registration of nanomaterials concludes that the information provided is extremely limited, and inadequate. One important hurdle for data submission in REACH and subsequently for data which is available for decision makers and competent authorities is the registration-threshold of 1 t/a and per manufacturer/importer for a substance in REACH. If a nanomaterial together with a chemically identical bulk material is manufactured or imported in quantities of 1 t/a or more, information on the nanomaterial should be available, too, even if the quantity of the registered nanomaterial is less than 1 t/a. This is due to the fact that all identified uses of a substance have to be registered (see Art. 10 (a) (iii) REACH), which includes uses below 1 t/a. However, if a nanomaterial is not chemically identical with a bulk material (e.g. carbon nanotubes with carbon), the nanomaterial itself must be manufactured or imported in quantities of 1 t/a or more in order to be registered. In any case REACH will not deliver data on: ¬ the application of a nanomaterial as the usage categories in REACH are very broad, ¬ the nanomaterial concentration in the respective product, and ¬ manufactured or imported tonnage bands of the nanomaterial(s) when registered together with the chemically identical bulk material.

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	5
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	4
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way	4
e) The establishment of national registries and notification schemes causes market fragmentation and	4

hampers trade within the internal market

Please provide additional comments

Authorities in the EU and in Members States are lacking the following information: ¬ Which products contain nanomaterials that are intentionally or unintentionally released? – Product and trade name requested for a NANOMTERIAL REGISTRY will help here; ¬ What kind of nanomaterial(s) is released? – functionality, application and characterisation of the used nanomaterial requested for a nanomaterial registry will help here; ¬ What is the amount of a nanomaterial that is intentionally or unintentionally released over all sectors? – produced and imported amount of nanomaterials and concentration of nanomaterials in a nanoproduct requested for a nanomaterial registry will help here. The afore mentioned lack of information is based on the analysis of data requirements in existing legislation which shows that in principle a clear line can be drawn between information available for competent authorities on the nanomaterial itself and on the information on nanomaterial(s) in a concrete product. On the one hand CLP, REACH and product-specific regulations excluded from the scope of REACH, like food and food additives or food contact materials, require information on the nanomaterial, e.g. on the name of the notifier, the name of the nanomaterial, the functionality and the characterisation of the nanomaterial. On the other hand authorities have no information on the product and trade name of specific products containing nanomaterial(s), the application, the manufactured or imported volume of nanomaterial(s) in products and the concentration of nanomaterial(s) in products. There are two exceptions from this picture which are the Cosmetic Regulation and the Biocidal Products Regulation (BPR) which in general require information on the nanomaterial and on products containing nanomaterials equivalent to the data requirements of the nanomaterial registry. This information deficit is not removed by existing product registers on the national level (e.g. Switzerland, Norway, Denmark or Sweden). These registers do not sufficiently provide an overview on the market with nanomaterials as they focus on dangerous substances/ mixtures and not on articles. Finally, the EU's rapid alert system for non-food consumer products (RAPEX) cannot be regarded as a moderate means that are equally effective by comparison with a mandatory reporting requirement. RAPEX enables market surveillance authorities to inform each other if measures are put in place with regard to a consumer product that presents a serious risk to consumer health and safety. However, it only

intervenes, in the event of a specific threat to human health. Hazards in the workplace and environmental hazards are not covered. Moreover, the RAPEX system does not enable the competent authorities to obtain an overview of nanoproducts available on the market and reporting via RAPEX tells them nothing about whether the product in question contains nanomaterials.

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

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I am not aware of any classified nanomaterials,

I am not aware of any DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials

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

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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):
Evidence of Carcinogenicity: A study done on the impacts of nano sized titanium dioxide on rats showed a significant increase in malignant lung tumours following chronic inhalation of the nanomaterial (Heinrich et al., 1995). The US National Institute for Occupational Safety and Health (NIOSH, 2011) also determined the same result. More recent research by NIOSH has also showed the potential for multi wall carbon nanotubes to increase the risk of cancer in mice exposed to a known carcinogen (Castranova et al., 2013). Evidence of pulmonary effects: Animal studies have linked inhalation of carbon nanotubes to inflammation in the nasal cavity, larynx and trachea as well as alveolar lipoproteinosis (deposition of surfactant like material in the alveoli) (Ma-Hock et al,. 2009).Other in vivo studies have linked single wall carbon nanotubes to pulmonary toxicity, namely granulomas in the lungs (Larn et al., 2004). The severity of these effects is concentration dependent (Ma-Hock et al., 2009). The danger of pulmonary disease is inversely proportional to the size of the particle, smaller the particle, the greater the danger (Poland et al., 2008). Several studies have found that multi wall carbon nanotubes can have a significant impact on biological activity (Muller et al., 2009). One study showed that long multi wall carbon nanotubes produced length dependent effects on a surrogate for the protective lining that covers many internal organs of the chest cavity (Poland et al., 2008).

organs of the chest cavity (Poland et al., 2008). Effects include inflammation, foreign body giant cells, and granulomas. Other in vivo studies found that long exposure to nanosilver particles via inhalation produced an inflammatory response and alterations to lung function (Sunget al., 2008). These findings are similar to others showing pulmonary effects of other nanomaterials (aluminium oxide, titanium dioxide, zinc oxide, copper oxide and nickel oxide (Cho et al., 2010). Endocrine effects: Several studies have observed effects of quantum dots on reproductive dysfunction, thyroid hormone signaling, estrogen receptor activation, and endocrine disrupting activity. Other studies have shown that metal and metal oxide nanoparticles may exert endocrine-associated toxicities. Reproductive toxicity: It has been demonstrated in vivo rats that nano titanium dioxide cross the blood-testes barrier and cause lesions in the testis and spermatogenesis (Gau et al., 2013). This study showed changes in gene expression and hormone levels. Studies have that pre pubertal males exposed to nano silver resulted in delayed puberty and the males had lower sperm concentrations and a higher frequency of abnormal sperms, changes in the morphology of the seminiferous epithelium, as well as changes to cell membrane integrity and mitochondrial activity (Mathias et al., 2014, Sleiman et al., 2013 and others). Trans generational effects have also been demonstrated in a study where mice were exposed prenatally to nano carbon, lower sperm counts were found in the second generation (Oraby et al., 2013). Environmental toxicity: The impacts of nanomaterials has also been shown to impact on the environment. There is evidence of silver nanoparticles causing harm to aquatic invertebrates under low concentrations (Aitken et al., 2009). Other studies confirm this as they show adverse responses of plans and micro organisms to low doses of silver nanoparticles applied in field experiments via a likely route of exposure, sewadge sludge application (Colman et al., 2013). Studies have also shown that carbon nanotubes can induce cell death in plants (Cong-Xian Shen et al., 2010). Recently, a research team has determined that some metalic nanopoarticles can enter the food chain (Hernandez-Viezcas., 2013). Cerium oxide can be taken up by food crops when present in the soil, this is then an accumulative process as these metals build up in the ecosystem. The researchers also showed uptake of zinc nanoparticles.

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

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Please explain (if any, please report the events and any scientific publication):
There has been a reported case in China where workers who are dealing with nanomaterials on a daily basis had undergone serious health issues: 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 (Song et al., 2009).
http://www.ncbi.nlm.nih.gov/pubmed/19696157
The report told of a 26-year-old chemist who used nickel nanoparticle powder at a work bench with no safety procedures in place such as a breathing mask or ventilation hood. Over time she began having throat irritation, facial flushing and nasal congestion. Her skin began to react to the nickel posts of her earrings and a belt buckle that touched her stomach. Medical tests showed that the scientist had developed an allergy to nickel. In time, she became unable to return to work due to her recurrent symptoms.
http://www.rawstory.com/rs/2014/05/13/poisoned-nanotech-scientists-case-exposes-unknown-dangers-ofnew- particles/

Q10: The establishment of an EU nanomaterial registry (tick the relevant box):	Would significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials , If appropriate, please explain further: An ENPR would enable public authorities/agencies and governments to gain a comprehensive overview of nanoproducts available on the market across all sectors affected, enabling them to draw various conclusions, e.g. on the amount of special nanomaterials used in products in various sectors or the possible exposure pathways for those nanomaterials. Subsequently, governments and public agencies can use such information to improve their law enforcement as well as to develop new or adjust existing research programs for eco- and humantoxicology tailored to the nanomaterials on the market and their possible exposure pathways. Companies would benefit from the ENPR by gaining more knowledge about the use of NMs throughout the product chain. Traceability of nanomaterials throughout the production chain is an important part for risk management for both producers and authorities. That way, all players are enabled to remove products containing nanomaterials from the market if they prove to be unsafe after all based on latest scientific findings. The instrument enables producers to duly perform their producer responsibility. Consumers would have the choice between products containing NMs and without NMs. In addition, increased transparency could retain trust in NM technologies. The ENPR would also be beneficial in that it will limit the distortion of the European markets from different parallel registers at national level. An ENPR which is built on present substance and product related regulations would cost notifiers (manufacturers, distributors etc.) significantly less than multiple independent registers potentially creating duplicate obligations.

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)**	d) They would search for more information, Please explain: Surveys have been undertaken in this area and they suggest that consumer mindset would not change, they would still purchase nano containing products. However often this is due to a lack of knowledge about nanomaterials and their potential health impacts. We therefore believe there would be an increase in consumer interest surrounding the issue which makes information on the product about nanomaterials contained increasingly important to maintain consumer trust as well as the availability of information about nanomaterials on a European nanomaterial register. In any case information on nanomaterials and their uses is the basis for public acceptance of nanomaterials and nanoproducts on the long run. An important condition for trust in a new technology is transparency, including active information about products and research projects regarding these products and nanomaterials. One of the central topics of consumers participating in the BfR´s Consumer Conference on Nanotechnology (http://www.bfr.bund.de/cm/350/bfr_verbraucherkonferenz_nanotechnologie.pdf) was the postulation to have graduated information offers on nanotechnology ranging from easy to understand general overview on nanomaterials and nanoproducts to scientific based and more complex information.
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)**	b) have no significant impact, Comments: Comments: Impact on the market would most likely be indirect: By increasing the interest of the public, and by increasing trust in regulatory authorities, this would have a beneficial impact on the market and on the overall public understanding and acceptance of NM. Publicly available information is required for the market development of nanomaterials, if there is no labelling and a nano-related accident were to occur or results of a new study were to show significant health impacts then there would be a backlash against nanotechnologies thus significantly hampering research and innovation. It is therefore critical that products are labelled and a consumer choice is enabled in this relatively untested area. No information or fragmented information on nanoproducts would have (and is having) the opposite effect as it would leave consumers with the impression that the high expectations linked to nanotechnology might not be fulfilled. The reasons for that are a decrease in the knowledge of consumers about nanoproducts on the market, their functioning and benefits and a loss of trust in regulation due to the invisibility of the producers and products.

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)

a) stimulate innovation (e.g. through increased consumer trust, increased awareness on nanomaterials)

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Comments:
A nanomaterial registry would provide well rounded, transparent information about nanoproducts to regulatory authorities which will create greater legal certainty in the market. Legal uncertainty has been highlighted by nano producing/ distributing companies as the main factor stifling innovation of nanotechnologies. A nanomaterial registry would also generate greater acceptance of products containing nanomaterials from consumers and remove the stigma around the technology. This will build trust in the market, not just for the consumers but the producers would be able to develop products and know if they abide to legal requirements allowing for heavier investment in nanotechnology and the market whilst ensuring health and environmental safety. Although compliance with the registry may involve administrative costs and burden, (in particular for SMEs), a European register would in fact reduce the compliance costs and burden as compared to the current need to comply with multiple national registers. Furthermore, an increased focus and consideration of potential health and environmental impacts of new materials would strengthen better innovation, focusing on the development and marketing of safer products, better adapted to consumer's expectation, providing a competitive edge to EU industry. The addition of a nanomaterial registry would encompass all member states in the EU market therefore market distortion would not necessarily have any impact. If anything it has a greater potential of increasing innovation as problematic nano containing materials will be replaced by less harmful nanomaterials. Research will drive innovation and competition to produce the best and safest products on the market.

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)

a) stimulate intra-EU competitiveness,

b) enhance the competitiveness of European companies against extra-EU companies

,

Please explain
A nanomaterial registry would encourage better innovation, greater investment will improve technologies and companies will be competing to produce the best product with the least environmental and health impact. Greater innovation of nanomaterials will cause the price of nanomaterials to fall due to advanced production techniques thereby encouraging competition in the market and the need for investment e.g. Electrical & Electronics (E&E) market witnessed a robust growth due to the large price decrease of carbon nanotubes and increase in mass production of nanomaterials. A nanomaterial registry may also encourage government support for nanotechnologies thus potentially providing funding, levies and tax breaks to encourage development of the right products. With an increase in innovation there will also be an increase in new market applications that nanomaterials can be involved in. As highlighted in the previous question the increased competition is expected to partially shape efforts to innovate by highlighting potentially existing or emerging hazards connected to individual products. Competition will gain public acceptance of nano products as organisations will be openly displaying their products and their non-hazardous properties, this will increase advertisement of products and will provide a greater awareness to the public whilst improving their corporate image. Additionally the positioning of competitors can be assessed with greater ease.

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.

A notification per use of a mixture/article would allow for full traceability across the supply chain, which would be beneficial for supply chain information, relevant to downstream users and distributors, as well as for workers and consumers. If a product is labelled with a product-specific notification number and additionally nanomaterials are named on the label of the product, the chances that consumers and regulators will be able to track nanomaterials containing products is likely to be higher than in the other options.
It will also help to keep tabs on new nanoproducts entering the market, which is of key importance when trying to measure the total exposure and potential environmental and health impacts of nanomaterials. Moreover it will help improving knowledge on substances in products along the supply chain as currently many organisations/suppliers are unsure as to whether their products/ semi-row materials contain nanomaterials or not.
The notification per substance present in multiple products is useful for regulators, and research agencies but isn't sufficient in allowing informed consumer choice. The process needs to be clear, effective and provide consumers and down-stream suppliers with robust information to gain consumer and civil society’s confidence on the nano-market.

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) , e) Distributors to consumers (e.g. retailers), Please explain: Full traceability across the supply chain is needed therefore notification requirements are going to be necessary from all actors involved in the production and distribution of a nano containing product. This is the best way of creating a market that encourages consumer choice by making them aware of the health impacts that nanomaterials may have. If the use of a notification system 'per substance' is introduced then there should be no issue in all actors providing the notification scheme to downstream users. A VAT system to track this would be effective as shown by the French system.
Q17: **The following should be subject to notification requirements (tick all that apply):**	a) Substances, b) Mixtures containing nanomaterials, c) Articles with intended release of nanomaterials , d) Articles containing nanomaterials without intended release , Please explain: If the product contains nanomaterials as defined by the EC definition then they should be required to have a notification as that is the reason the nano registry has been devised. All information about nano containing products has to be provided to consumers to allow for an informed choice. The question of release also relates to the life cycle phase considered. The registration is necessary if there are releases anticipated at any stage of the life cycle of the product. Furthermore, even when no release is foreseen, information about this material/pro

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.) One of the objectives of such a register is to provide an accurate picture of the market situation to the regulator. In that respect, it appears unwise and unjustified to exclude any nanomaterial ex ante from the registration scheme.
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.) National schemes of nanomaterial registries in Belgium and Denmark have shown that it creates a lot of legal uncertainty for all stakeholders if certain uses of nanomaterials are exempted from the notification requirements. Attempts to exclude uses encompass, for example nanomaterial bound in a matrix or nanomaterials in products that are not intended to be released. However, from a life-cycle perspective and regarding the protection of the environment it is not certain that nanomaterials will stay in the matrix. It might be more useful to group and comment on certain types of nanomaterials in the public communication of the registry results, e.g. information on nanomaterials that are unlikely to be released during the use or after disposal.

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):
Information about potential health and environmental impacts as well as environmental fate of said material. In general, a Nanomaterials Observatory can only provide added value beyond existing studies on nanomaterials on the EU market if the following information is publicly available: ¬ Application of the nanomaterial, ¬ Functionality of the nanomaterial(s) employed, ¬ Characterisation of nanomaterial(s), ¬ Nanomaterial concentration in the respective product, and ¬ Manufactured or imported tonnage bands of the nanomaterial(s).

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

We need to generate statistical data on these products.
A good way could be to set up a visual tool that works like google map (you can zoom-in and out) and you can, by region, find out the amount of nanomaterial containing products are produced, sold and disposed. Data should be easily aggregated and exported via a public available website.

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
,

e) Informed purchasing decisions by consumers,

f) General education of the public,

g) Other purposes (please specify)
Safe disposal, reuse and recycling of products containing NMs. Enhance the acceptance of the safe use of nanomaterials in products.

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):

A notification scheme based on the use of substances would be more useful in the context of risk assessment scenario. A life cycle assessment of each product also needs to be carried out in order to evaluate the risk of nano containing products over their whole life cycle, especially in the manufacturing and disposal phase. Information should support regulatory authorities in developing legislation to protect workers (who are generally exposed to higher concentrations of nanomaterials for extended periods of time). Regulators will also be able to develop strategies assessing the use of nanomaterials in greater detail, this will only serve to enhance the safe use of nanomaterials in the market. A registry of products will ensure that companies know exactly what is present in their products, this information will be transparent and will therefore drive companies to promote the safe use of nanomaterials in their products in order to compete in the market. A nano registry provides consumer choice of products allowing them to choose nano, non-nano or different nanomaterials ensuring a greater control from consumers, which is one of the main aims of the registry. Increased information in relation to nanoproducts will undoubtedly increase awareness of the market thereby improving education of the public about the matter at hand.

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

As described in various legal studies such as “just out of REACH, how reach is failing to regulate nanomaterials and how it can be fixed”, or the ECHA analysis of nano registration so far, REACH contains gaps and loopholes when it comes to nanomaterials, and as a result, REACH has not so far delivered any meaningful information on nanomaterials. Such a register would address this issue. It would furthermore achieve traceability of all NMs in products arriving to the EU. Finally, a nanomaterial registry could be a good control tool to verify the correct registration of nanomaterials according to REACH requirements.

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

A weighing up of the costs and benefits of an ENPR is only possible to a limited extent. This is not only due to the uncertainties the researched costs and benefits have but also to the methodological disparities of quantitative estimation of the direct costs for notifiers and public authorities compared with a qualitative estimation of the benefits. Moreover the character of the ENPR as a precautionary instrument makes a comparison of costs and benefits rather difficult. The costs of preventive actions are usually tangible, clearly allocated and often short term, whereas the costs of failing to act are less tangible, less clearly distributed and usually longer term, posing particular problems of governance. (see “late lessons from early warning 2: Science, precaution, Innovation” in particular section C, available @ http://www.eea.europa.eu/publications/late-lessons-2