Summary of the public consultation on transparency for nanomaterials on the market

This text is an excerpt of the options assessment report by RPA and BiPRO in the context of the study to assess the impact of possible legislation to increase transparency on nanomaterials on the market. It is made available in advance of the publication of the full report for the purpose of reporting on the public consultation results.

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1 Respondents

1.1 Industry respondents

There were 98 completed questionnaires from industry respondents across Europe and further afield. There was a 50:50 split between individual companies and industry associations.

93 industry respondents provided details of their organisation including a country location (see **Table 1-1**).

Table 1-1: Location of Industry Respondents					
Responses	Countries				
31	Germany				
29	Brussels				
9	France				
6	United Kingdom				
2	Finland, Netherlands, Spain, Switzerland				
1	Czech Republic, Denmark, Italy, Japan, Lithuania, Nigeria, Norway, Portugal, Sweden, United States of America				

Of these 93 respondents, 50 indicated that they were listed on the EU's Transparency Register¹ and provided their ID number. Of those that were on the Transparency Register, most were industry associations, often based in Brussels.

1.2 Responses from Member State authorities

There were 12 completed questionnaires from Member State authorities across Europe. These comprised five responses from federal and regional authorities in Germany and one from each of France, Denmark, UK, Italy, Belgium, Estonia and Sweden.

1.3 Responses from citizens

There were 74 completed questionnaires from citizens and citizen groups from across Europe and some responses from further afield. The make up of the 74 respondents is shown in (see **Table 1-2**).

Table 1-2: Nature of Citizen Respondents							
Responses	Nature of Respondent						
39	A consumer organisation/trade union/environmental organisation/non-governmental						
33	organisation						
35	An individual						

Of these 74 respondents, 17 indicated that they were listed on the EU's Transparency Register and provided their ID number. Of those that were on the Transparency Register, most were in the first category of Table 1-2 ('consumer organisation/trade union/environmental organisation/non-governmental organisation') often based in Brussels.

Table 1-3 (next page) indicates the location of the respondents.

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http://ec.europa.eu/transparencyregister/info

Table 1-3: Location of Citizen Respondents						
Responses per Country	Countries					
25	France					
13	Belgium					
5	Denmark, Sweden					
4	Germany					
3	UK					
2 Australia, Netherlands, Norway. Switzerland, USA						
1	Brazil, Bulgaria, Finland, Ghana, Hungary, Japan, Mexico, Poland					
Note: One respondent did not provide a specific country						

1.4 Other respondents

There were 15 completed questionnaires from other respondents from across Europe. The make up of these 15 respondents is shown in **Table 1-4**.

Table 1-4: Nature of Other Respondents					
Responses	Nature of Respondent				
5	A health and safety institute/academic organisation/research organisation				
10	Others				

Of these 15 respondents, one indicated that they were listed on the EU's Transparency Register and provided their ID number. **Table 1-5** indicates the location of the respondents.

Table 1-5: Location of Other Respondents					
Responses per Country	er Country Countries				
6	France				
2	Germany, Netherlands				
1	Belgium, Bulgaria, Ireland, Spain, Switzerland				

1.5 Note on responses

At the outset of this analysis, it is important to stress that most respondents not only provided the minimum answers required but also many additional comments. Indeed, for most questions, over 60% of respondents provided such comments.

All of the comments have been read and considered. In the report that follows, efforts have been to summarise the key points highlighted by respondents in relation to each of the issues being addressed. For those wishing to examine these comments in depth, the Commission has published all responses to the public consultation² (where the respondent was content for their contribution to be published).

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http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/public-consultation_en.htm

2 Supply Chain Characterisation (Industry Respondents)

2.1 Overview

16 (16%) industry respondents indicated that they had participated in the online survey (undertaken by RPA/BiPRO for the European Commission in early 2014) on the administrative burden of existing notification schemes. These respondents were therefore not asked for detailed information on their operations and proceeded to questions on 'problem definition and objectives' (see Section 3).

The remaining 82 industry respondents were asked for further information on their activities. As already noted there was an approximate 50:50 split between companies and associations.

A profile of the industry respondents is presented in **Table 2-1**.

Table 2-1: Profile of Industry Respondents					
Our company or member company	% Industry Respondents (n=79)				
has to notify to the French Notification System	61%				
has to notify to the Cosmetic Products Notification Portal	28%				
is a manufacturer of nanomaterials	58%				
is an importer of nanomaterials	54%				
is a formulator of mixtures containing nanomaterials	66%				
is a manufacturer of articles containing nanomaterials without intended release	51%				
is a manufacturer of articles containing nanomaterials with intended release	11%				
is a distributor of nanomaterials and/or mixtures containing nanomaterials	41%				
is a distributor of articles containing nanomaterials	23%				
None of the above	9%				
Not sure whether we deal with nanomaterials	9%				

2.2 NACE codes

59 respondents provided some information on the four-digit NACE code of their primary business sector and 27 provided some information on the four-digit NACE code of their secondary business sector. Because some of the respondents (both companies and associations) had a range of interests, it was difficult for them to provide one (or two) specific codes.

Overall, it appeared that the primary activity of about half of the respondents could be classified as 20xy (Manufacture of chemicals and chemicals products).

2.3 Company size

Although many of the industry respondents were (or represented) large companies with more than 250 employees, a significant portion were (or represented) small and medium enterprises (SMEs) as summarised in **Table 2-2**.

Table 2-2: Company Size by Employees						
Number of Employees	% Industry Respondents (n=63)					
1-9 employees (micro enterprise in terms of employees)	6%					
10-49 employees (small enterprise in terms of employees)	16%					
50-249 employees (medium enterprise in terms of employees)	8%					
≥ 250 employees (large enterprise in terms of employees)	70%					

A similar picture emerged when considering total turnover and turnover associated with nanomaterials as summarised in **Table 2-3**.

Table 2-3: Company Size by Turnover						
Trumparay Value	Annual	Nano-related				
Turnover Value	% Respondents (n=53)	%Respondents (n=40)				
<€250k (micro enterprise in terms of turnover)	9%	15%				
<€2m (micro enterprise in terms of turnover)	2%	3%				
€2m to €10m (small enterprise in terms of turnover)	8%	10%				
€10m to €50m (medium enterprise in terms of						
turnover)	9%	13%				
≥ €50m (large enterprise in terms of turnover)	72%	60%				

2.4 Markets for nanomaterials

Respondents were asked to indicate the number of nano-related products (where these include nanomaterials (NMs) as well as mixtures (Mixt) and articles containing nanomaterials (Art)) which they (or the companies they represent) place on the national, EU and global markets. The results are summarised in **Table 2-4**.

Table 2-4: Markets for Nanomaterials									
Newshau of Duadesta	Nat	National market		EU market		Global market			
Number of Products	NMs	Mixt	Art	NMs	Mixt	Art	NMs	Mixt	Art
Less than 6	63%	29%	35%	66%	21%	33%	58%	18%	28%
Between 6 and 10	15%	0%	0%	10%	6%	0%	15%	9%	6%
Between 11 and 50	4%	6%	0%	3%	6%	0%	4%	6%	0%
Between 51 and 100	0%	12%	0%	3%	12%	6%	4%	12%	6%
Between 101 and 250	0%	3%	0%	0%	6%	0%	0%	6%	0%
Between 251 and 500	4%	3%	6%	3%	3%	6%	4%	3%	6%
Between 501 and 1,000	0%	3%	6%	0%	6%	6%	0%	6%	6%
Over 1,000	15%	44%	53%	14%	41%	50%	15%	41%	50%
Number of Respondents	27	34	17	29	34	18	26	34	18
Note that products are identified as nanometerials (NIMs), mixtures (Mixt), and articles containing									

Note that products are identified as nanomaterials (NMs); mixtures (Mixt); and articles containing nanomaterials (Art)

It is apparent from **Table 2-4** that most respondents were either specialising in a few products or were involved with a very wide of range of products. It is also worth noting that there appear to be few significant differences between the geographical types of market.

A similar picture emerged when considering numbers of suppliers and customers³. In other words, most respondents had either few suppliers/customers or had a large number of suppliers/customers as shown in **Table 2-5**.

Table 2-5: Numbers of Customers/Suppliers						
Number	% Respondents Customers	% Respondents Suppliers				
Less than 6	10%	27%				
Between 6 and 15	2%	27%				
Between 16 and 30	5%	10%				
Between 31 and 50	0%	3%				
Between 51 and 100	5%	17%				
Over 100	78%	17%				
Number of Respondents	41	30				

The extent to which these results are influenced by responses from associations rather than individual companies is being investigated.

3 Problem Definition and Objectives

3.1 Objectives of possible intervention

Respondents were asked to rate the importance of the possible objectives (see **Table 3-1**) on a scale between 1 and 5 (1-not important at all / 5-very important).

Table 3-1:	Objectives of Possible Intervention
А	Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials
В	Provide consumers with relevant information on products containing nanomaterials on the market
С	Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
D	Ensure consumer trust in products containing nanomaterials
E	Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market
F	Ensure the proportionality of the information requirements and the associated costs and administrative burden
G	Protect confidential business information

The responses are illustrated overleaf (**Figure 3-1**). By inspection, it can be seen that there was a consensus amongst all stakeholders that *Objective A - Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials was very important.*

There was also general consensus that *Objective D - Ensure consumer trust in products containing nanomaterials* was either very important (rating of 5) or of considerable importance (rating of 4).

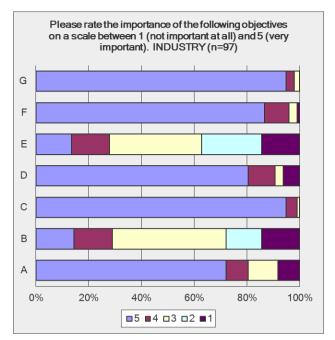
Industry stakeholders considered three further objectives to be very important while most MS Authorities considered that these were either very important (rating of 5) or of considerable importance (rating of 4):

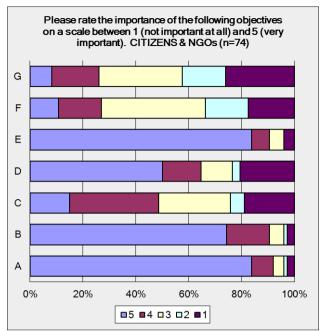
- Objective C Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
- Objective F Ensure the proportionality of the information requirements and the associated costs and administrative burden
- Objective G Protect confidential business information

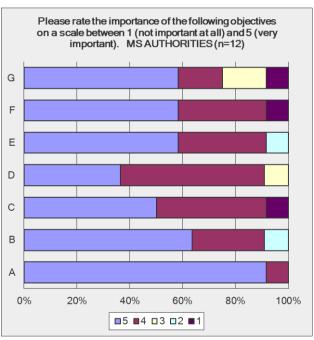
Citizens and NGOs and other stakeholders indicated that the remaining two objective were very important (with significant support also from MS Authorities):

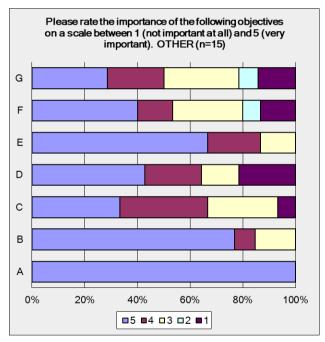
- Objective B Provide consumers with relevant information on products containing nanomaterials on the market
- Objective C Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market

Figure 3-1: Importance of Objectives









Key:

- G Protect confidential business information
- F Ensure the proportionality of the information requirements and the associated costs and administrative burden
- E Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market
- D Ensure consumer trust in products containing nanomaterials
- C Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
- B Provide consumers with relevant information on products containing nanomaterials on the market
- A Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials

In the additional comments provided, the predominant message from industry was that nanomaterials should be regarded in the same way as other substances, with REACH and other legislation applying only when appropriate. According nanomaterials different treatment (e.g. providing consumers with information on products containing nanomaterials even if safe has used has been demonstrated) will result in a stigmatisation of nanomaterials, with a negative effect on consumer trust. There was also concern that informing consumers about the presence of nanomaterials in a product offers little benefit if the specific impact of that material in a product is not known. Finally, there was underlying concern that the measures should not create a heavy administrative burden with duplication of work and that they should not reveal confidential information.

There was a widespread view amongst responses from citizens and NGOs that, in the interest of the health of consumers and workers, and to a lesser extent the environment, the precautionary principle should be borne in mind concerning the unknown implications of exposure to nanomaterials. Stakeholders made the link between building consumers' trust and providing relevant information on products containing nanomaterials, whether through labelling of products or a dedicated registry. Such transparency was highlighted as essential for building consumer trust and facilitates informed decision making.

Further comments from some of the MS Authorities stressed that while there remained some uncertainties, it was important to retain the principle of proportionality.

3.2 Do existing legislation/databases meet objectives

Respondents were asked to rate the degree (from 1 - not at all to 5 - fully) to which the current legislative framework (including the REACH and CLP Regulations and product-specific legislation) and the currently available databases (including the JRC web platform) meet particular objectives (as listed in **Table 3-2**.

Table 3-2: [Do Existing Legislation/Databases meet Objectives
А	Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials
В	Provide consumers with relevant information on products containing nanomaterials on the market
С	Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
D	Ensure consumer trust in products containing nanomaterials
E	Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market
F	Ensure the proportionality of the information requirements and the associated costs and administrative burden.
G	Protect confidential business information

The responses are illustrated overleaf (**Figure 3-2**). By inspection, it can be seen that there was a consensus amongst all stakeholders that *Objective G - Protect confidential business information* was being met (predominance of ratings 4 and 5).

Thereafter, there was a divergence of views with industry respondents being more favourable towards the existing framework. Industry respondents considered that (in addition to Objective G), a further two objectives were being met:

- Objective A Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials
- Objective E Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market

On the other hand, other stakeholders (MS authorities, citizens and NGOs, and others) were of the view that these two objectives were not being met (predominance of ratings 1 and 2). These stakeholders also considered that a further two objectives were not being met:

- Objective B Provide consumers with relevant information on products containing nanomaterials on the market
- Objective D Ensure consumer trust in products containing nanomaterials

There appeared to be a diverse a range of opinions (both within and amongst different stakeholder groups) with respect to the remaining two objectives:

- Objective C Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
- Objective F Ensure the proportionality of the information requirements and the associated costs and administrative burden

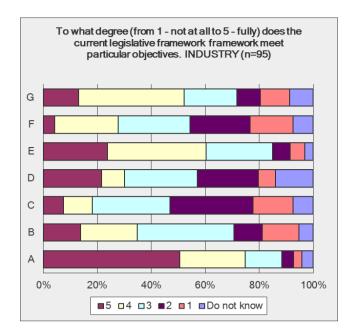
Industry respondents were keen to stress in their additional comments that the current legal regime is appropriate, noting that this is the most comprehensive framework applicable to nanomaterials in the world. With this in mind, consumer trust could be improved through better implementation of these measures alongside explanatory dialogue with consumers. To introduce additional requirements would constitute an administrative burden for companies, with no guarantee of a potential positive impact on the supply chain or consumer trust. Moreover, further requirements may negatively impact the competitiveness and innovative capacity of the chemical industry.

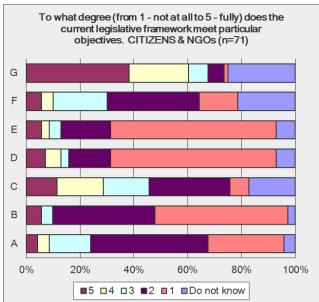
Industry respondents also noted that the objectives in question may be better met if the definition of nanomaterials, implementation registers and measuring methods were more closely defined and clarified.

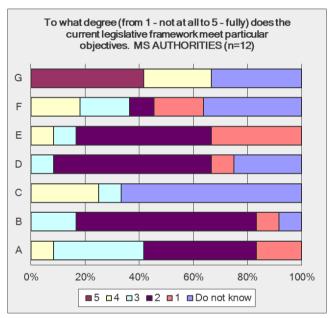
In general, comments from citizens and NGOs noted that that there is currently no legislation or database which provides adequate or standardised information concerning products which contain nanomaterials on the European market. Moreover, this is predominantly limited to food, cosmetics and biocides. In their responses, stakeholders frequently referred to REACH but were generally of the opinion that the information on nanomaterials recorded under this legislation is extremely limited and inadequate — a view shared by several MS authorities. It was felt that REACH is not sufficiently adapted for nanomaterials given the absence of a definition, a tonnage band restriction of 1 tonne per annum and the fact that it considers nanomaterials to be identical to the bulk material.

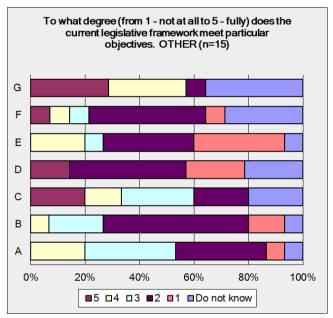
The JRC web platform was referenced by several stakeholders and is generally seen as being complicated, incomplete and not user friendly for consumers.

Figure 3-2: Do Existing Legislation/Databases meet Objectives?









Key:

- G Protect confidential business information
- F Ensure the proportionality of the information requirements and the associated costs and administrative burden.
- E Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market
- D Ensure consumer trust in products containing nanomaterials
- C Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
- B Provide consumers with relevant information on products containing nanomaterials on the market
- A Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials



3.3 Views on information on nanomaterials

Respondents were asked to rate their agreement with various statements (see **Table 3-3**) from 1 (strongly disagree) to 5 (strongly agree).

Table 3-3:	Views on Information on Nanomaterials
А	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
В	The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for informed consumer choice
С	The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust
D	The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way
Е	The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market

The responses are illustrated overleaf (**Figure 3-3**). By inspection, it can be seen that there was strong agreement from industry with considerable agreement (mostly ratings 4 and 5) from MS authorities and, to a lesser extent, from citizens and NGOs and other stakeholders for:

• Objective E - The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market

There was strong agreement from citizens and NGOs with strong/considerable agreement from MS authorities and other stakeholders (but not industry) for two objectives:

- Objective 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
- Objective 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

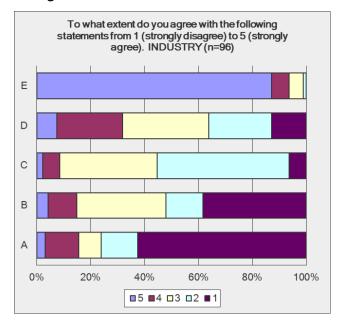
There was also considerable agreement (mostly ratings 4 and 5) from MS authorities, citizens and NGOs and other stakeholders (but not industry) for the remaining two objectives:

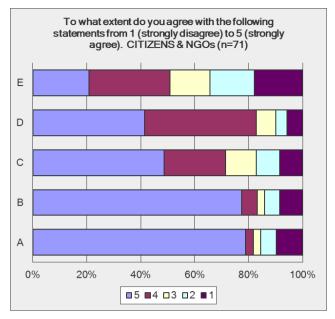
- Objective C The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust
- Objective D The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way

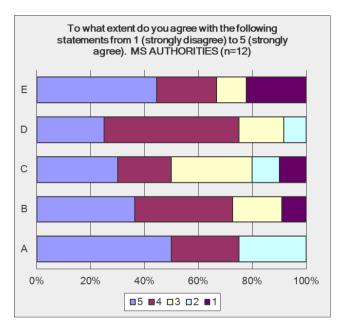
Further comments provided by industry reflected the responses presented above, with respondents noting that national schemes create obstacles to trade within the internal market. Indeed, many cited the French notification system, which it is claimed has imposed a high burden (effort and cost) on industry, particularly SMEs. Industry respondents also claim that the presence of other national schemes in Belgium and Denmark has only made matters worse. However, several MS authority respondents noted that there was a lack of evidence to provide robust opinions on such issues.

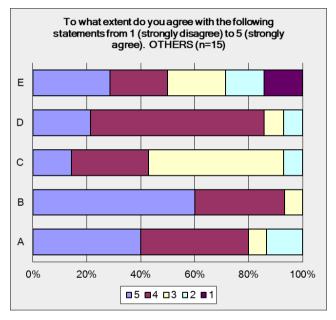
Industry also noted that an adequate response to health and environment risks is not achieved by providing information on the presence of nanomaterials in a product, but by an effective and reliable risk assessment of the nanomaterial (as foreseen by REACH and product-specific regulations).

Figure 3-3: Views on information on nanomaterials









Key:

- E The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market
- D The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way
- C The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust
- 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
- 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

Finally, with respect to industry respondents, regulatory provisions for nanomaterials (substances) used as cosmetic ingredients and for cosmetic products that contain these nanomaterials, cover all of the objectives of a potential EU nanomaterial observatory/registry.

Conversely, additional comments provided by citizens and NGOs again highlighted that the current legislative framework is not particularly suited for nanomaterials, leading to insufficient information regarding the risk to the health of consumers and workers. Many of the stakeholders highlighted the need for an EU wide registry of products containing nanomaterials, rather than the disjointed national registries, which have further compounded the issue of inconsistent and incomparable data collection across the EU. It was commented that the establishment of an EU wide register would not only build consumer trust but would also ensure that authorities can conduct their roles effectively.

4 Health and Environmental Aspects

4.1 Awareness of issues

With regard to health and environmental hazards and risks of specific nanomaterials/types of nanomaterials, respondents were asked whether or not they were aware of particular issues associated with nanomaterials as shown in **Table 4-1**.

Table 4-1: Awareness of issues				
	% respondents			
I am aware of	Industry (n=92)	MS Auth'ties (n=12)	Citizens & NGOs (n=67)	Other (n=15)
health and/or environmental hazards of specific nanomaterials/types of nanomaterials	89%	92%	93%	87%
specific nanomaterials that are classified as hazardous under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	54%	50%	21%	20%
DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials	60%	58%	15%	20%
significant exposure of workers/users/ consumers to specific nanomaterials/types of nanomaterials	37%	50%	85%	60%

There was a high level of awareness of health and/or environmental hazards across all stakeholders. There was a reasonable level of awareness of specific classifications and limit values amongst both industry and MS authority respondents – but this level of awareness was not shared by citizens and NGOs and other stakeholders.

There was a high level of awareness of significant exposures amongst citizens and NGOs and, to a lesser extent, amongst MS authorities and other stakeholders.

Supplementary comments provided by industry acknowledged that hazards may be associated with some nanomaterials, but that nanomaterials are no more hazardous than other chemicals. Here it was asserted that the hypothesis that smaller means more reactive and thus more toxic is unsubstantiated by the published data. Over 60% of citizen and NGO respondents provided further comments related to the health and environmental effects of nanomaterials. The health effects frequently mentioned were carcinogenicity, pulmonary effects, endocrine disruption, reproductive toxicity, anti-microbial resistance and environmental toxicity. Several MS authorities cited examples of hazards and limit values associated with specific nanomaterials.

Industry respondents noted that although consumers may be exposed to nanomaterials in products (e.g. cosmetics), such products are subject to an official risk assessment and authorisation. Similarly, workers may also be exposed to nanomaterials, but safety is ensured through the application of personal protection measures (e.g. personal protective equipment) safety protection measurements and exposure limit values.

Many industry respondents also cited examples of nanomaterials for which DNELS and reference values have been set, the most frequent being titanium dioxide (TiO2), carbon nanotubes and nanowires. Specific nanomaterials identified by non-industry stakeholders where concerns exist include zinc oxide (in sun screens), titanium dioxide, nanosilver and carbon nanotubes. More

specifically, the risk to workers through occupational exposure was highlighted. Several stakeholders provided particular examples of DNELs, PNECs and OELs in Member States.

4.2 Awareness of incidents

With regard to the past and current use of nanomaterials, respondents were asked whether or not they were aware of particular health and/or environmental incidents which have occurred as shown in Table 4-2.

Table 4-2: Awareness of Incidents					
	% respondents				
Response	Industry (n=95)	MS Auth'ties (n=11)	Citizens & NGOs (n=65)	Other (n=12)	
I am aware of health and/or environmental incidents which have occurred	14%	45%	61%	42%	

Reflecting the results in Table 4-2, the majority of industry respondents were unaware of health or/and environmental incidents associated with nanomaterials. Where incidents involving nanomaterials have been reported, industry respondents advocated that the hazard itself was not attributable to the nanoscale dimension of the substance and that the exposure was caused by failure to comply with appropriate safety precautions.

It would appear from comments by citizens and NGOs that the main means of raising the awareness of the health and environmental effects of nanomaterials are laboratory research involving animal studies, *in vitro* and *in vivo* toxicological experiments and human case studies of occupational or accidental exposure. Stakeholders reported on a number of chronic and acute illnesses which have been linked to short-term and prolonged exposure to nanomaterials. These ranged from allergies, burns, cancer, pulmonary effects, endocrine effects and reproductive toxicity.

Two specific reported cases of exposure to nanomaterials were highlighted by a number of respondents. The first was that of several workers in China who were exposed to nanomaterials for 5-13 months and experienced shortness of breath and pleural effusions. The other reported case was that of a 26 year old chemist working with nickel nanoparticle powder and subsequently developed a nickel allergy and was unable to return to work due to recurrent symptoms. From stakeholder responses, it appears that most cases relating to the health effects of nanomaterials results from occupational exposure. However, it was pointed out by some that, due to the lack of information available, employers may be unaware that their staff are handling nanomaterials and consequently the necessary precautions are not taken. The environmental effects were mentioned less frequently.

4.3 Impact of nanomaterials registry

With regard to establishment of an EU nanomaterials registry, respondents were asked whether or not it would contribute to reducing the risks. The responses are summarised in **Table 4-3.**

Table 4-3: Impact of nanomaterials registry				
	% respondents			
Response	Industry (n=94)	MS Auth'ties (n=12)	Citizens & NGOs (n=70)	Other (n=14)
[A nanomaterials registry] would significantly contribute to reducing the	2%	75%	74%	36%

health and/or environmental risks related to		
the use of nanomaterials		

Industry respondents were of the view that risks posed by nanomaterials can be controlled by implementing the current European framework (REACH, CLP and sectoral legislation). The added value of an EU registry as regards controlling the potential risks posed by nanomaterials is considered to be negligible, since it would not contribute to the identification of risks and is therefore unlikely to improve safety. Rather, a registry is likely to create additional burdens, particularly for SMEs, and will create a negative public perception of nanotechnologies.

Nevertheless, several industry respondents acknowledged that an EU-wide registry would be preferable to 28 national registries.

In contrast, MS authorities, citizens and NGOs considered that a registry would make a significant difference. Further comments from MS authority (and some 'other') respondents suggested that an EU-wide registry would provide useful information on the use of nanomaterials through their lifecycle. This, in turn, would assist with assessments of exposure and risk as well as identifying appropriate risk management measures.

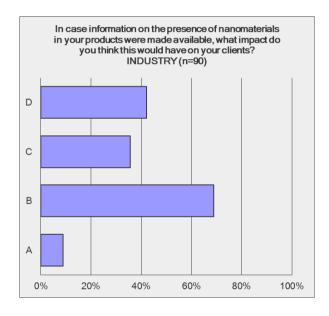
Such views were reiterated by citizens and NGOs with an emphasis on the need for a registry to provide for vigilance across the production chain and enhance the availability of information to all users.

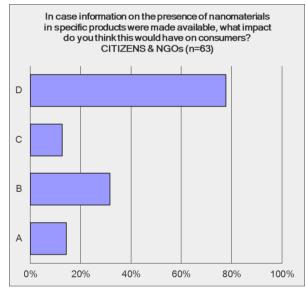
5.1 Impacts on consumer behaviour

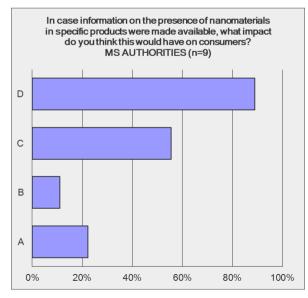
With regard to the provision of information concerning presence of nanomaterials in products, respondents were asked as to the potential reactions (as listed in **Table 5-1**) of customers with the results shown in **Figure 5-1**.

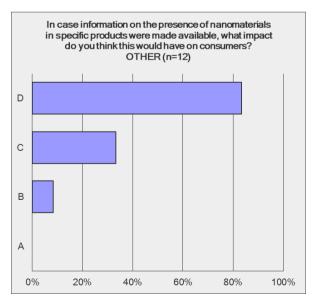
Table 5-1: Imp	pacts on Consumer Behaviour
Α	They would be more inclined to purchase those products
В	They would try to avoid those products
С	Their purchasing decisions would not be affected
D	They would search for more information

Figure 5-1: Impacts on consumer behaviour









There was a consensus that the provision of information concerning presence of nanomaterials in products would not lead to consumers being more inclined to purchase those products (Statement A).

Indeed, industry respondents noted that as a result of negative preconceptions and the current stigma associated with nanomaterials, providing information about the presence of nanomaterials in a product to consumers could result in them avoiding that product. In fact, many respondents found this to be the case following implementation of the French notification scheme for nanomaterials. Further evidence of the negative stigma associated with nanomaterials is evident in the requests from customers for products free from nanomaterials. On the other hand, in many instances the French notification scheme would appear to have had no impact on the purchasing decision (Statement C) and in some instances, companies will promote the presence of nanomaterials in their product. (e.g. high-tech product).

Other industry respondents noted that the information indicating the presence of nanomaterials in products would result in customers, particularly business clients, requesting further information such as an explanation or assessment on the safety of the product.

Of note is that the responses from citizens and NGOs suggested that consumers were more likely to search for more information (Statement D) rather than to simply avoid the products (Statement B) and this view was shared by MS authorities and other respondents.

Further comments from citizens and NGOs, MS authorities and other respondents suggest that there are many factors to consider with regard to the impacts of labelling products with nanomaterials (e.g. type of product, type of nanomaterial, utility, etc.). However, providing information concerning the presence of nanomaterials will stimulate interest in some consumers, who will then be likely to search for further information so that they can make an informed and conscious choice. Other respondents noted that the purchasing decision of some consumers would be unaffected because of a lack of knowledge of nanomaterials and their potential health impacts. Finally, some consumers would perceive 'nano' as a selling point, while there would be those consumers concerned about the health impacts of certain nanomaterials that would avoid such products.

5.2 Impacts on consumer attitudes

Respondents were asked to consider the likely impacts of information on the presence of nanomaterials in products. The responses are summarised in **Table 5-2**.

Table 5-2: Impacts on Consumer Attitudes					
Information on the presence of	% Respondents				
nanomaterials in products would	Industry (n=90)	MS Auth'ties (n=9)	Citizens & NGOs (n=57)	Other (n=10)	
generate trust among consumers and the broad public, and thus have a positive effect on the market for the concerned products	0%	55%	39%	40%	
have no significant impact	16%	33%	40%	30%	
generate insecurity or stigmatise such products, and thus have a negative effect on the market for the concerned products	84%	11%	21%	30%	

As is evident from Table 5-2, the majority of industry respondents believe that providing information on the presence of nanomaterials will result in adverse feeling towards the product. This is because there is a lack of consumer knowledge coupled with predefined negative views of nanomaterials. Consequently, such a label may confuse consumers, with there being the possibility for them to interpret the information as a warning label.

However, it was also noted by some industry respondents that cosmetics products are already labelled with a full list of ingredients, including nanomaterials, and there has, to date, been no significant impact on consumer behaviour.

A number of MS authorities and citizens and NGOs stated that information on the presence of nanomaterials will improve transparency, which is one of the first steps to establishing consumer trust. Other citizens and NGOs noted that openly disclosing the presence of nanomaterials carries the risk of stigmatising products, with companies and consumers choosing to boycott them.

6 Innovation and Competitiveness

6.1 Impacts on innovation

With regard to innovation, respondents were asked as to the likely impacts of information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry. From **Table 6-1**, it is apparent that there are very divergent views amongst stakeholders.

Table 6-1: Impacts on Innovation					
Information on the presence of	% Respondents				
nanomaterials in products would	Industry (n=93)	MS Auth'ties (n=10)	Citizens & NGOs (n=62)	Other (n=12)	
stimulate innovation (e.g. through increased consumer trust, increased awareness on nanomaterials)	2%	60%	71%	50%	
have no significant impact on innovation	13%	10%	26%	25%	
hamper innovation in the EU (e.g. through concerns about confidential business information or through additional costs related to providing information)	85%	30%	3%	25%	

Many industry respondents were concerned that providing information about the presence of nanomaterials in a product would negatively impact nanotechnology innovation. A number of respondents noted that the French national registry system undermined economic partners' trust in nanomaterials, which in turn negatively impacted competitiveness and innovation. It also brought uncertainties amongst economic actors towards the French market, raising question marks with regard to business developments and the location of research and development activities in France.

More generally, it was noted that imposing requirements to provide further information would increase administrative burden across the whole supply chain, resulting in additional costs that would otherwise be spent on research and development. This could deter the emergence of further nanomaterial producers or alternatively, they may choose to locate themselves outside of the EU.

Numerous industry respondents also stressed that any requirement to provide information must be carefully balanced against the need for confidentiality. A failure to strike the right balance could negatively impair innovation. On the other hand, it was also noted that dissemination of information on nanomaterials could result in better knowledge of their properties, particularly around hazard and handling guidelines, which could stimulate innovation.

Citizens and NGOs and, to a lesser extent, MS authorities and other respondents, believe that information provision would stimulate innovation. Many respondents stated that, by labelling products that contain nanomaterials, greater legal certainty would be created in the market. This is important because legal uncertainty has been highlighted by nano producing/distributing companies as one of the main factors stifling the innovation of nanotechnologies. Indeed, a registry would encourage the commercialisation of products that are both safer and meet the needs of consumers. This alongside additional transparency has the potential to secure a market for the long term, and it is this that will prove to be the source of innovation.

6.2 Impacts on competitiveness

With regard to competitiveness of EU companies manufacturing nanomaterials or products containing nanomaterials, respondents were asked as to the likely impacts of information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry. From **Table 6-2** and **Table 6-3**, it is apparent that there are very divergent views amongst stakeholders

Information on the consequence of	% Respondents			
Information on the presence of nanomaterials in products would	Industry (n=90)	MS Auth'ties (n=10)	Citizens & NGOs (n=63)	Other (n=11)
stimulate intra-EU competitiveness	1%	30%	57%	55%
have no significant impact on intra-EU competitiveness	19%	70%	19%	18%
hamper intra-EU competitiveness	44%	10%	5%	18%
Table 6-3: Impacts on Extra-EUCompetitiv	eness			
Information on the process of	% Respondents			
Information on the presence of nanomaterials in products would	Industry (n=90)	MS Auth'ties (n=10)	Citizens & NGOs (n=63)	Other (n=11)
enhance the competitiveness of European companies against extra-EU companies	3%	40%	57%	27%
have no significant impact on the	3%	30%	19%	9%
competitiveness of European companies against extra-EU companies	3%			

Industry respondents commented that a nanomaterial registry would severely disadvantage EU companies. EU companies would be required to register their nanomaterials at all stages of development and processing whereas those companies outside of the EU would only have to register products once they enter the EU market. The additional burden placed upon intra-EU companies would thus give companies outside of the EU a competitive advantage. It was also suggested that the costs of complying with the additional requirements would be borne by consumers, which would result in increased prices for value chains in EU vs non-EU markets.

MS authorities questioned whether there would be any intra-EU impacts on competitiveness as the same requirements would be imposed on all companies within the EU. In fact, it may stimulate innovation as the registry may encourage government support for nanotechnologies in the form of funding, levies and tax breaks to encourage development of the right products. The view that intra-EU competitiveness would be stimulated was supported by most citizen and NGO and other respondents. However, it was noted that the French registry hampered competition immediately following its introduction, but this was only temporary and receded following the correct control on importation and dialogue. In any event, providing adequate information to consumers should far outweigh the consideration of market impacts, as a health crisis may be detrimental for the EU industry in the long term.

Although most citizen and NGO indicated that extra-EU competitiveness would also be enhanced, MS authorities and other respondents were more cautious in their responses.

7 Possible Impact of a Registry on Companies (Industry Respondents)

7.1 Perceived impacts

Industry respondents were asked as the likely effects of a possible obligation to notify nanomaterials at the EU level assuming that no exemptions were to be made from 1 (no impact) to 5 (significant impact). These ratings were used to derive an overall weighted score⁴ for each impact which were then ranked as shown in **Table 7-1**.

Significance of impacts resulting from an obligation to notify nanomaterials at the EU level	Rank	% "Significant impact"
with respect to nanomaterials in mixtures	1	77%
with respect to articles containing nanomaterials in general (i.e. in case also articles without an intended release of nanomaterials were to be covered)	2	60%
with respect to nanomaterials on their own	3	45%
with respect to articles with intended release of the nanomaterials	4	28%

With regard to engineered nanomaterials in Europe, the market is currently nascent with one of the major producers of nanotubes selling less than 200 tonnes of nanotubes in Europe. Conversely, the volume of conventionally used materials that may fall under the definition of a nanomaterial is potentially much bigger (e.g. there is around 47 million tonnes of plastics produced within the EU).

Considering articles that contain nanomaterials in general and the matter of intended release, industry respondents noted that nanomaterials may be 'fixated' in the product via binding materials. However, it may be the case that the product would peel or flake, perhaps as a result of abrasion, but the size of any peelings or flakes are unlikely to fall within the definition of a nanomaterial. Nevertheless, one respondent claimed that research and development in one sector was stopped because of uncertainty as to whether the product would fall within the definition of a nanomaterial. Although it was acknowledged that it is difficult to define what constitutes an article containing nanomaterials without intended release, to prevent significant impacts (e.g. deterring research and development), it was suggested that such products should be beyond the scope of notification. Another respondent was primarily concerned that confidential business information could be compromised by not excluding such suppliers.

If the significance of any impacts is measured in terms of the breadth, then consideration should be given to those who commented that pigments and fillers are present in nearly every product and article of our daily life. Consequently, nearly every product and article would need to be registered if there was no exemption. Specific responses from different sectors included:

 within the paint and printing ink more than 500,000 mixtures would be affected annually in Germany alone;

Weighted scores are derived by summing N(i) x i where N(i) is the number of respondents scoring i. By way of example, suppose 3 people rated the first objective as a 1 (no impact), 2 people rated it as a 3 and 4 rated it as a 5 (significant impact), then the weighted score would be: $(3 \times 1) + (2 \times 3) + (4 \times 5) = 29$.

- for dental manufacturers of mixtures and articles, the obligation of notification would impact an estimate 90% of all dental materials (e.g. materials usually contain nano-scale fillers (aerosol) to tune the viscosity of any paste like material);
- the automotive industry uses nanomaterials in substances and mixtures and the notification requirement would add an additional burden with questionable effect;
- within the chemical industry, EU notification would mainly impact substances and mixtures, although nanomaterials are sometimes already embedded in a matrix at production level, which could be considered part of articles. This information would need to be provided to article producers, with the burden also placed upon suppliers; and
- any additional notification within the cosmetics industry would create an additional burden without added benefits.

7.2 Business confidentiality

98% of the 87 industry respondents to this question indicated that a disclosure of the notified information would conflict with the confidentiality of business information.

Industry respondents commented that much would depend on the extent of disclosure and specific information that would need to be submitted. Of most concern for industry was the possibility of revealing the name or description of the substance, as competitors may not be aware that a substance can exist at nanoscale. Other comments related to:

- information linked to substance identify (characterisation of the nanomaterial);
- the uses:
- · the quantities put on the marker; and
- name of the customers.

7.3 Expected difficulties with national schemes

91% of the 87 industry respondents to this question indicated that they experience or expect significant barriers to their company/members of their association from diverging notification obligations in the schemes in France/Belgium/ Denmark.

Industry respondents reported that multiple national schemes would increase the administrative and bureaucratic burden as a result of each database having its own scope, requirements and definitions, which means time must be spent gathering and inputting relevant information. There may also be linguistic barriers.

7.4 National markets

86% of the 77 industry respondents to this question indicated that there is not any significant difference amongst EU national markets for their nanomaterials and/or products containing nanomaterials.

Industry respondents commented that there may be differences in the respective administrative burden associated with marketing a particular product in a Member State as a result of national specific registers. The extent of industrial development within a Member State may also result in differences between EU markets. Finally, the market for plastics with nanomaterials has declined due to the cost of materials and fears that the regulatory burden will increase.

7.5 Elements of best practice

Industry respondents were asked: In case the European Commission were to recommend a best practice model for national notification schemes based on the experiences in France, Belgium and Denmark, which elements of these systems can be considered as "best practice"?

The vast majority of the 75 industry respondents were not positive in their responses stating that there was no national 'best practice'. However, some respondents commended the Danish system because it only required essential information, concerns only consumer products and exempts cosmetic ingredients and products. The way in which the French system is linked to substances according to REACH was also praised, specifically its use of the REACH number instead of the creation of a new (national) notification number. This aspect of the notification scheme helped downstream users, particularly SMEs, to reduce the administrative burden if the same substance is bought from different suppliers.

8 Possible Options and Exemptions

8.1 Type of notification

Respondents were asked about the added value of a notification per use (i.e. for each mixture/article) compared to a notification per substance?

Views from 90 industry respondents were largely negative. The majority of respondents stated that there would be no added value of notification per use when compared with existing regulations (e.g. cosmetic regulation, food information/regulation, biocides) as the information for downstream user companies and workers is already covered by safety data sheets. For this reason, many industry respondents did not provide responses to the next two questions (see Sections 8.2 and 8.3 below) which concerned the scope of potential notifications.

Where comments were positive, it was noted that this approach could be a good start for the nanomaterials observatory. Notification per use may also be more appropriate for mixtures as the conditions of use may impact the health and environmental risks. Notification per use may also allow for better estimation of potential exposure routes (oral, inhalation, dermal).

10 MS authority, 57 citizen and NGO and 12 other respondents provided additional comments, with many commenting that notification per use would enable full traceability and the tracking of nanomaterials along the supply chain, as well as the monitoring of new nanoproducts that enter the market. A further added value of notification per use is the availability of information on both uses of, and exposure to, nanomaterials in different situations.

However, several MS authorities noted that such a requirement could lead to a significant administrative burden. Indeed some suggested that an annual notification scheme would lead to an unmanageable stream of information, with it suggested that this was one of the main reasons for the failure of the former EU existing chemicals regulation (793/93/EEC).

8.2 Notification along the supply chain

Respondents were asked about which actors along the supply chain should be subject to notification requirements as summarised in **Table 8-1**.

Table 8-1: Notification along the Supply Chain				
	% Respondents			
Notification should apply to	Industry* (n=52)	MS Auth'ties (n=11)	Citizens & NGOs (n=65)	Other (n=14)
Manufacturers of nanomaterials	96%	100%	95%	100%
Importers of nanomaterials	96%	100%	97%	93%
Downstream users (e.g. re-formulators, manufacturers of products containing nanomaterials)	40%	82%	92%	86%
Distributors to professional users (e.g. wholesalers)	10%	36%	86%	65%
Distributors to consumers (e.g. retailers)	10%	9%	89%	50%

*Note that many industry respondents did not consider that such notifications are merited and did not respond to this question

Industry respondents were of the view that manufacturers (and importers) were the only actors likely to know the exact content of product, and therefore only they were capable of providing the relevant information. Furthermore, the burden should be on them as they bring the materials to market within the EU. It was also noted that with regard to these issues, downstream users were covered by sectoral legislation (e.g. cosmetic regulation contains nano-notification scheme).

MS authorities and other respondents were of the view that the notification requirements should extend beyond manufacturers and importers to include downstream users (e.g. re-formulators, manufacturers of products containing nanomaterials). Several MS authorities noted that such requirements would correlate with the requirements of the REACH Regulation.

For their part, citizens and NGOs indicated that all actors within the supply chain should be subjected to notification requirements to ensure information is effectively conveyed to consumers. A full understanding of the production chain would allow for a life cycle assessment of products containing nanomaterials. This would ensure that all possible impacts are systematically discovered (e.g. workers can take appropriate preventative measures to protect themselves).

8.3 Subject of notification

Respondents were asked about which nanomaterials and associated products should be subject to notification requirements as summarised in **Table 8-2**.

Table 8-2: Subject of notification				
	% Respondents			
Notification should apply to	Industry* (n=40)	MS Auth'ties (n=11)	Citizens & NGOs (n=66)	Other (n=14)
Substances	88%	91%	93%	93%
Mixtures containing nanomaterials	40%	100%	97%	93%
Articles with intended release of nanomaterials	43%	91%	97%	93%
Articles containing nanomaterials without intended release	10%	36%	86%	57%

^{*}Note that many industry respondents did not consider that such notifications are merited and did not respond to this question

Industry respondents commented that the currently regime is sufficient, with several regulatory frameworks (e.g. REACH, Cosmetics Regulation) already requiring notifications. Reflecting the responses in Table 8-2, it was also noted that to ask for information on all articles (even those with no intended release) may lead to overarching vague notifications that would detract from the value of a notification system.

The majority of non-industry respondents believe that notification for nanomaterials should apply to all substances, mixtures or articles that may contain nanomaterials — although most MS authority respondents were not persuaded to extend the scope to include articles containing nanomaterials without intended release. It was noted that experience from the French registry, which excludes nanomaterials whose release is not intentional, has resulted in some nanomaterials that may pose a risk to health or the environment being excluded (e.g. nanosilver). With this in mind, respondents stated that to exclude these nanomaterials would create legal uncertainty in the interpretation of what is intended release and unintended release. Moreover, information on articles where release is not intended would still be relevant to workers in order to implement workplace risk management measures.

8.4 Exemptions

Respondents were asked whether there should be exemptions for certain types and/or for certain uses of nanomaterials. The responses are summarised in **Table 8-3.**

Table 8-3: Exemptions				
	% Respondents			
Response	Industry	MS Auth'ties	Citizens & NGOs	Other (n=14)
Yes, certain types of nanomaterials should be exempted from a notification system	89% (n=74)	50% (n=10)	11% (n=65)	21%
Yes, certain uses of nanomaterials should be exempted from a notification system	92% (n=71)	78% (n=9)	7% (n=62)	29%

Greatest support for exemptions was provided by industry, followed by MS authorities and other respondents. Responses from citizens and NGOs were strongly against granting exemptions.

A number of industry respondents again reiterated that a notification was unnecessary and all nanomaterials should be exempted. Specific examples of types and/or certain uses of nanomaterials to be exempted included:

- nanomaterials that are integrated into the matrix and will not be released during use (e.g. pigments, fillers and plastic);
- naturally existing nanomaterials (e.g. iron oxides) or those with a long history of use (e.g. inorganic fillers, pigments);
- nanomaterials not intentionally manufactured to the nano-scale.

Several MS authorities commented that exemptions (for materials and uses) could be considered provided a full assessment of the associated risks demonstrated safe use. Several citizen and NGO respondents noted that such assessments would need to cover the whole life cycle, especially in the manufacturing and disposal phase.

Examples of specific types of nanomaterials to be exempted that were cited by non-industry respondents included:

- dental materials, as no evidence exists for a risk to patients and users; and
- liquid nanoparticles such as micelles in mayonnaise.

Examples of nanomaterials to be exempted that were cited by <u>both</u> industry and non-industry respondents included:

- nanomaterials subject to other legislation (e.g. e.g. REACH, CLP, Cosmetic Regulation, Biocides Directive) on the basis that information on the nanomaterial is already available;
- uses of nanomaterials associated with (scientific) research and development as they are often used in low quantities and compliance would burden research laboratories.

As is clear from Table 8-3, most citizen and NGO respondents thought it was better not to exclude any types or uses of nanomaterials, as it would undermine the purpose of the registry, which is to provide an accurate and transparent picture of the market situation to the regulator and to improve the knowledge for risk assessment (hazard assessment and characterization of exposure).

Moreover, the national schemes in Belgium and Denmark have demonstrated that legal uncertainty can arise if certain uses of nanomaterials are excluded from the notification requirements. More generally, responses from citizens and NGOs commented that a notification scheme based on the use of substances would be more useful in the context of risk assessment scenario.		

9 Structured Approach to Collect Information ("Nanomaterials Observatory")

9.1 Information to be collected

Respondents were asked what type of information (as listed **Table 9-1**) should be collected for a Nanomaterials Observatory should this be established instead of an EU-wide registry.

Table 9-1: Information to be Collected		
Α	Information from existing notification systems	
В	Information from market studies on nanomaterials and products containing nanomaterials	
С	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	

As can be seen from **Figure 9-1** (next page), there was a much greater degree of coherence amongst respondents. In particular, there was general agreement that the following items should be collected:

- A Information from existing notification systems
- E Information on the hazards and risks of nanomaterials

There was also general agreement amongst MS authorities, citizens and NGOs and other respondents, with a slightly lower level of support from industry respondents, for a further two items to be collected:

- B Information from market studies on nanomaterials and products containing nanomaterials
- C Information on the use of nanomaterials across Europe

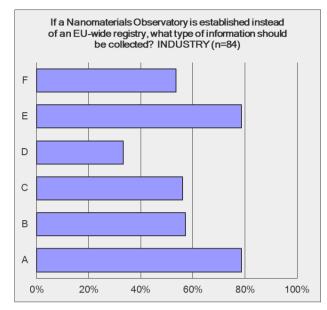
Although there was also general agreement amongst MS authorities, citizens and NGOs and other respondents for *information concerning products containing nanomaterials* to be provided, this was not supported by industry respondents.

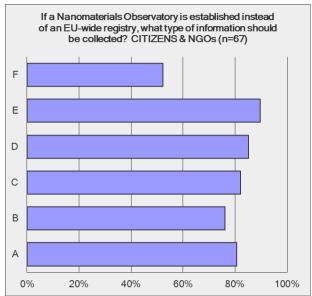
Industry respondents commented that information established in an observatory should be taken from existing sources (e.g. current regulatory schemes and voluntary submissions) rather than from new and/or additional legislation. Comments from several MS authorities noted that an observatory could be a useful information resource (for example by incorporating FP7 research project findings).

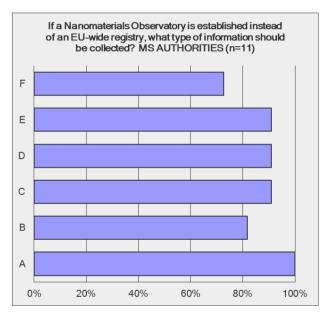
Citizen and NGO respondents commented that the type of information to be collected would be linked to the purpose of the observatory. If the primary objective of the observatory is transparency and traceability, risk information may be less important. Of course, if the aim of the observatory is to ensure the safe use of nanomaterials throughout the supply chain, risk information is essential. To provide added value, an observatory should collect information on the:

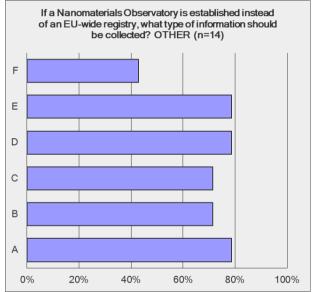
- application of the nanomaterial;
- functionality of the nanomaterial(s) employed;
- characterisation of nanomaterial;
- nanomaterial concentration in the respective product; and
- manufactured or imported tonnage bands of nanomaterial.

Figure 9-1: Information for a Nanomaterials Observatory









9.2 Information presented

82 industry, 11 MS authority, 53 citizen and NGO, and 13 other respondents provided views on how the information in a Nanomaterials Observatory should be presented in order to reach the consumers, workers and authorities.

Industry respondents commented that information collated from all current regulatory schemes could be brought together and made available to consumers in a format that can be easily accessed, such as the German DaNa⁵. Alternatively, this information could be presented to consumers in the

⁵ http://www.nanopartikel.info/en

form of market studies. For workers and authorities, more detailed safety information would be useful.

There was a general consensus amongst MS authorities, citizens and NGOs and other respondents that information presented should be suitable for the user and tailored for targeted groups.

Specific examples suggested included:

- booklets produced by independent and objective experts;
- a comprehensive online database that is searchable, can be easily navigated by consumers and is available in all EU languages;
- product labels; and
- an interactive map (similar to, for example, the European Pollutant Release and Transfer Register (E-PRTR)) that would, by region, indicate the quantities of nanomaterials:
 - imported
 - manufactured
 - handled in businesses
 - distributed
 - marketed and used by workers and consumers
 - destroyed/recycled

10 Potential Use and Benefits of a Nanomaterial Registry

10.1 Information uses

Respondents were asked in what ways the information on nanomaterials from registries would be potentially useful (as listed in **Table 10-1**) and the results are shown in **Figure 10-1** (overleaf).

Table 10-1: Potential Information Uses		
Α	Risk assessment and/or risk management	
В	Enforcement of worker protection	
С	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)	

The majority of responses from industry reiterated the view that a registry for nanomaterials is not necessary as the current EU regulatory regime is sufficient. However, it was noted that it may be a means to educate the general public and raise the awareness of nanomaterials and their safe use in products.

Over 80% of citizen and NGO respondents considered that all the uses specified in **Table 10-1** would be potentially useful.

MS authority other respondents were slightly more cautious with over 75% of respondents identifying four items as being potentially useful:

- 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

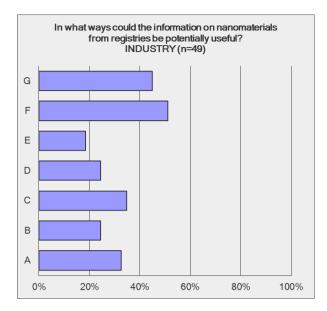
Further comments from MS authority respondents suggested a range of further potential uses, including:

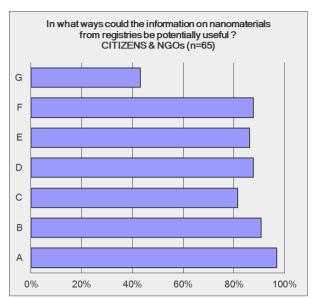
- prioritising policy actions regarding nanomaterials
- assisting with assessing insurance requirements/responsibilities
- raising awareness of risk and risk management amongst employers
- · improved traceability of nanomaterials

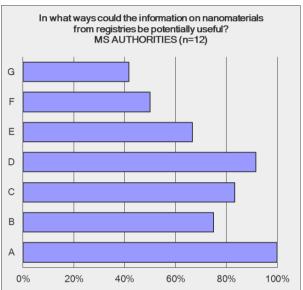
Several citizens and NGOs repeated the same suggestion that a nanomaterials registry would:

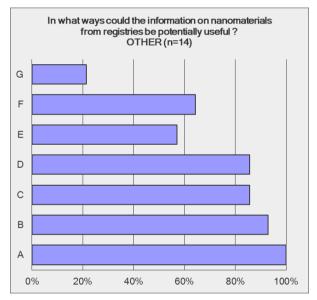
assist with the safe disposal, reuse and recycling of products containing nanomaterials

Figure 10-1: Information Uses









10.2 Added value

Respondents were asked in to indicate the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration.

Comments were provided by 89 industry respondents, who were predominantly sceptical as to the added value of a European nanomaterial registry, although it was noted that an EU registry is more beneficial than multiple national registers.

Comments were provided by 11 MS authority and 14 other respondents, who were mainly of the view that the prime added value of a European nanomaterial registry would be to extend the information already collected under REACH in two main areas. Firstly, there would be an explicit reference to the presence of nanomaterials and, secondly, a registry would not need to be restricted by the current one tonne per annum threshold which applies to chemicals under REACH.

Comments were provided by 57 citizen and NGO respondents, who were largely positive about the potential added value that a European nanomaterial registry may bring. Many stakeholders noted that a registry may redress the gaps and loopholes that exist with REACH with regard to nanomaterials. Here it was suggested that REACH has failed to deliver significant information on nanomaterials, in part because of the threshold of 1 tonne which is not relevant for nanomaterials. An EU registry would also harmonise the information about formulations or products that contain nanomaterials.

More generally, citizen and NGO respondents noted that transparency is essential to build public trust and ensure that nanomaterials are properly regulated. Transparency will also assist with product recalls, should this measure ever need to be undertaken. Of course an EU registry is not the sole option, with product labelling an alternative or perhaps complimentary means of achieving this goal.





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