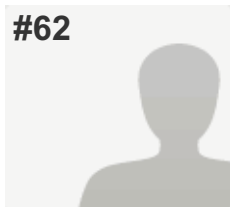


#62



COMPLETE

Collector: Nano Consult - Industry (Web Link)

Started:

Last Modified:

Time Spent:

IP Address:

PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):

Organisation*:	FEB/VBO (Federation of Enterprises in Belgium)
Town/City:	Brussels
Country*:	Belgium
Contact name:	Vanessa Biebel
E-mail address:	
Transparency Register ID number (if applicable)	47676761061-93

Q2: 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

Q3: We might need to contact you to clarify some of your answers. Please state your preference below:

I am available to be contacted

Q4: Did your organisation participate in the online survey (undertaken by RPA/BiPRO for the European Commission in early 2014) on the administrative burden of the notification schemes?

No

PAGE 3: Section II - Organisation Information

Q5: Please indicate which of the following applies to you or your members (tick all that apply):

- a) has to notify to the French Notification System
- ,
- b) has to notify to the Cosmetic Products Notification Portal
- ,
- c) is a manufacturer of nanomaterials,
- d) is an importer of nanomaterials,
- e) is a formulator of mixtures containing nanomaterials
- ,
- f) is a manufacturer of articles containing nanomaterials without intended release
- ,
- g) is a manufacturer of articles containing nanomaterials with intended release
- ,
- h) is a distributor of nanomaterials and/or mixtures containing nanomaterials
- ,
- i) is a distributor of articles containing nanomaterials

Q6: Please indicate the four-digit NACE code of your primary and secondary business sector (if applicable). If you require information regarding NACE codes, please visit the European Commission Competition webpage at http://ec.europa.eu/competition/mergers/cases/index/nace_all.html

Respondent skipped this question

Q7: Please indicate the number of employees.

Respondent skipped this question

Q8: Please indicate the approximate annual turnover of your organisation and the annual turnover which relates to nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials).

Respondent skipped this question

Q9: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the national market.

Respondent skipped this question

Q10: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the EU market.

Respondent skipped this question

Q11: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the global market.

Respondent skipped this question

Q12: Please indicate the number of customers and, if applicable, number of suppliers for all your nano-related products combined (where these include nanomaterials as well as mixtures and articles containing nanomaterials). *Respondent skipped this question*

PAGE 4: Section III – Problem definition and objectives

Q13: 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 | 2 |
| c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs) | 5 |
| 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 | 2 |
| f) Ensure the proportionality of the information requirements and the associated costs and administrative burden. | 5 |
| g) Protect confidential business information | 5 |

Please provide additional comments

Nanomaterials (NMs) should be regarded as any other substance. In that context, as required by REACH for instance, data should be gathered by industry in order to perform risk assessments and ensure protection of workers and the environment as well as safe use of the products that are placed on the market. By this way, with relevant explanation on the process provided to workers and the public, trade union and consumer trust could be increased. Specific legislation (that applies also to nanomaterials) concerning worker safety and environment already exists. Specific legislation covering sensitive products containing nanomaterials, like cosmetics or biocides, already require information for consumers and health authorities. Also via the IUCLID database, consumers have access to nanomaterials registered under REACH and their potential application. An inventory is not the right tool for consumer communication. In general, existing workers safety legislation and environmental legislation is also applicable on nanomaterials, although not explicitly mentioned in the text. From discussions in

the 5 High Councils in order to prepare their advice on the Belgian nano-register it became clear that both trade unions and consumers supported the idea of a nano-register. Industry should therefore address both, the concerns of both workers (trade unions) and consumers (consumer NGOs) in order to establish a stable and long lasting trust of both workers and consumers in nanomaterials. One should take into consideration that most consumers are also workers. On the contrary, providing to consumers information on products containing NMs that are placed on the market could lead to a stigmatisation of NMs, with a negative effect on consumer trust, even if safe use is demonstrated by the implementation of the relevant regulations (REACH and/or sector-specific legislation). However, it is important to communicate to downstream users, particularly when safety is a concern. An inventory is not the right tool to communicate to consumers.

Q14: 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 | 4 |
| b) Provide consumers with relevant information on products containing nanomaterials on the market | 3 |
| 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 | 2 |
| e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market | 4 |
| f) Ensure the proportionality of the information requirements and the associated costs and administrative burden. | 4 |
| g) Protect confidential business information | 4 |

Please provide additional comments

We believe that, as for any other substance, consumer trust can be increased by a good implementation of the current European legislative framework (even if some adaptations in the REACH annexes are needed), provided that it is well explained to the public. Additional requirements would constitute an administrative burden for companies with no guaranty of a potential positive impact on consumer trust. Negative consequences on the competitiveness and the innovation capacity of the chemical industry can nevertheless be expected, as shown by the current cosmetics legislation requirements.

Q15: 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 | 1 |
| 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 | 3 |
| c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust | 2 |
| d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or | 3 |

on the market is presented in an incoherent or ineffective way

e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market

5

Please provide additional comments

There should be clear distinction between the availability of hazard and risk info on a NM and information available on a certain NM present in a 'product' (mixture/article). It is unlikely that consumers themselves can assess the hazards and risks of NM. Therefore the necessary information for health and environment should be available to the authorities, as is regulated in the current European legislative framework. Moreover, the different reports of the national schemes are expected to increase even more the incoherent way of presenting information on presence of nanomaterials in certain products. As consumers will find out that in certain countries a product is listed and in others the same product not, which will add to the confusion. As regards question e), on the basis of the experience gained by the chemical industry in France with the French notification scheme and discussions during the development of a Belgian scheme, VBO/FEB confirms that such a national system creates obstacles to trade within the internal European market, especially when in Belgium a notification is required before the placing on the Belgian market of the product. The definition and the scope is not applied the same way in these countries and metrology skills do not guarantee harmonised interpretation. ~~xx~~ Therefore policy option 1 [Recommendation on how to implement a "best practice model" for Member States wishing to establish a national system] is absolutely not a realistic approach for industry because this will lead to many mutually different national nano-registration systems inside the EU resulting ultimately in a very large burden for industry as already demonstrated by different the French, German and Danish nano-registration obligations plus the nano-registration requirements in EER member Norway (that also introduced REACH)

Q16: With regard to health and environmental hazards and risks of specific nanomaterials/types of nanomaterials, please tick the relevant boxes:

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

,

I am aware of specific nanomaterials that are classified as hazardous under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

,

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

,

I am not aware of any significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials

,

Please explain your responses (if any, please report the nanomaterials, the health and/or environmental hazards, any relevant classification, any DNELs/PNECs/OELs, any exposure and in which condition):
Where consumer exposure occurs with sunscreens or biocides, the products are subject to an official risk assessment and authorization. The same will apply eg for medical devices containing nanomaterials once the draft regulation on medical devices will be approved.

Q17: With regard to the past and current use of nanomaterials (tick the relevant box):

I am not aware of any health and/or environmental incidents which have occurred

Q18: The establishment of an EU nanomaterial registry (tick the relevant box):

Would not significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials

,

If appropriate, please explain further:
VBO/FEB believes that risks can be controlled by the implementation of the current European regulatory framework [REACH, CLP, health and safety (both consumers and workers), environment and sectoral legislation], even if we acknowledge that amendments of REACH Annexes may be needed. Indeed, this framework foresees hazards identification requirements, risk assessment methodologies and ensures safe use of NMs that are placed on the market (as such, in mixtures and in articles). Moreover, for hazardous NMs, traceability can be ensured via the Safety Data Sheet (REACH art 31) or other communication (REACH Art 32 and Art 33) as regards industrial and professional users. Hence, we do not see the added value of an EU registry as regards risks control.

Q19: In case information on the presence of nanomaterials in your products were made available, what impact do you think this would have on your clients? (Please tick all that would apply)

b) They would try to avoid those products,

Please explain:

Clients may be "Downstream Users" and "Consumers" or both together. . In case of Downstream Users: companies and workers will have to apply the Risk Reduction Measures described in de Safety Datasheet and eventual accompanying Exposure Scenario as required by the "REACH DU obligations" of REACH 37-39. . In case of consumers (with no education or knowledge about nanomaterials) the information provided may result in avoiding the concerned products due to "fear for the unknown". Generally outside professional users, there is poor knowledge about nanomaterials in products and the benefit they bring. This could lead to a priori negative feeling in the general public. The implementation of the French notification scheme for NMs showed that situations b) occurred within the supply chain. Clients wanted to avoid products containing NMs either due to the administrative burden of the notification system or due to the "black-list" effect led by the stigmatisation of NMs with such a scheme. Nano-free products are already requested. However depending on cultural basis or businesses (higher in the value chain), some would not be affected.

Q20: 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)

c) generate insecurity or stigmatise such products, and thus have a negative effect on the market for the concerned products

,

Comments:

Depending on consumer knowledge, nanomaterials can be interpreted as a threat or a benefit. Generally outside professional users, there is poor knowledge about nanomaterials in products and the benefit they bring. This could lead to a priori negative feeling in the general public. However dialogue with end users have shown that there is no big interest in nanotechnology at this level. Appropriate and timely communication is needed to overcome a priori feelings in public eyes. Variability among countries is also a reality.

Q21: 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)

c) hamper innovation in the EU (e.g. through concerns about confidential business information or through additional costs related to providing information)

,

Comments:

The additional administrative burden within the whole supply chain will request resources that are hence not spent on looking for new opportunities and markets, and innovation and R&D. This is especially true for SMEs. This was indicated by companies during the Belgian impact assessment for a nano-inventory.

Q22: 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)

f) hamper the competitiveness of European companies against extra-EU companies

,

Please explain

There is no reason a priori to consider that a register is needed for nanomaterials: they are not more or less hazardous than any other chemical. Asking for a register would create a burden on that specific industry producing, importing or using nanomaterials when competing with other non-nano substances. In addition the cost of such register would most probably be borne by consumers so entailing increased prices for value chains in EU vs non-EU markets. The effect would be even stronger when industry would have to deal with several national registers. Intra-EU competitiveness would be hampered in this case.

Q23: Overall, how would a possible obligation to notify nanomaterials at the EU level affect your company/the members of your association, assuming that no exemptions were to be made from 1 (no impact) to 5 (significant impact):

- | | |
|--|---|
| a) with respect to nanomaterials on their own | 5 |
| b) with respect to nanomaterials in mixtures | 5 |
| c) with respect to articles with intended release of the nanomaterials | 4 |
| d) with respect to articles containing nanomaterials in general (i.e. in case also articles without an intended release of nanomaterials were to be covered) | 5 |

Please explain:

The impact assessment of the Belgian inventory is available at summary of the impact assessment done by BiPro The report mentioned (p13) 'In general, for the entire supply chain, the number of unique products is as follows: there are around 2000-5000 unique substances, 80,000-160,000 unique preparations, and 800,000-1,300,000 unique articles containing NMs' and ' For all sectors evaluated, the number of companies placing a NM-containing product on the market was estimated to be between 35,000-45,000 enterprises. This represents approximately 15-20% of all the enterprises in Belgium according to 2011 data from the Belgian National Social Security Office' (p11). In case of complex articles this will lead to very high burdens for EU industry (such as cars, trains, ships, airplanes, complex machinery, electric and electronic devices) consisting of many subcomponents and containing also substances and mixtures brought together for final assembly via a long, complex, intertwined and international supply chain involving nearly all countries of the world.

Q24: Would disclosure of the notified information conflict with the confidentiality of business information?

Yes, there would be a conflict with business information confidentiality

,

If yes, please elaborate; you may differentiate according to the different information that may be required in a notification scheme (e.g.: if a notification is only per substance and general use, or if the exact use needs to be disclosed): Indeed, several confidential information could be disclosed with such a notification scheme: - The name of the substance itself as sometimes competitors don't know that a substance can exist at nanoscale - The information linked to the substance identity (characterisation of the NM) - The uses - The quantities put on the market - The name of the customers If reporting/dissemination of information is considered, only aggregated data can be used; Despite of all protective measures taken there will always be a risk of industrial espionage via computer viruses collecting sensitive data from an eventual EU or national register. The fruits of many years of investment in R&D may be lost when sensitive data are leaked from a nano-register.

Q25: Do you experience or expect any significant barriers for your company/members of your association from diverging registration obligations in the schemes in France/Belgium/Denmark?

Yes, we foresee significant barriers,

If yes, please describe these barriers? Diverging obligations not only increase the workload, but also add to the possible confusion in the supply chain as supply chains are not 'only national'. Companies with sites in different member states, will probably get different information. A significant barrier in Belgium is the obligation to register before the placing on the Belgian market. As other schemes merely monitor what has been put on the market the previous year, this will be confusing and might lead to products on the market where the registration has not been done on time. The Belgian scheme has a clause that 'mutual recognition' with other national schemes can be pursued. This would reduce the burden within non-national supply chains as a customer can rely on the number of the supplier while making his notification without having the supplier to have to notify again to the Belgian scheme. Product related topics should preferably be handled at EU level not to hamper the intra-EU market by different national schemes.

Q26: Is the market for your nanomaterials/products containing nanomaterials significantly different from Member State to Member State?

Yes, the markets differ at national level,

If yes, please describe these differences
Companies making products for the whole EU market may be forced to meet at high cost the strictest criteria of each of the national requirements in order to sell one and the same product in the whole internal market of the EER, or be forced to make also at high costs specific products adapted to the specific requirements of each national legislation. The longer and more complex, and the more international the supply chain is the more difficult this will be.

Q27: 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”?

- Use of the same nanomaterial definition, same criteria, same test methods and identical interpretation by national inspections.
- Transmission of the notification numbers along the supply chain in order to minimize the burden for companies and protect confidential information
- Maintain the registration number as long as no changes occur to the characterisation of the NM (as in Belgium) (which is not the case in France adding to an additional yearly communication of the new registration number)
- Staggered deadlines if subsequent ‘supply chain stages’ (substance, mixture, article) would be considered to allow the info to be communicated in the chain
- mutual recognition of a notification done in another national scheme
- Consider as much as possible information as Confidential Business Information in order not to hamper more competitiveness and innovation

PAGE 9: Section VIII – Possible options and exemptions

Q28: 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.

communication in the supply chain would always refer to a ‘nanomaterial-substance’. Irrespective of the notification, a safe use of the product must be assessed under the current legislative framework, which do not only cover the placing on the market, but as well the occupational hygiene and health of workers. Information to protect the workers can be found in the safety data sheets, so an inventory would not bring any added value.

We consider use notifications per mixture or per article (if this is defined as a ‘use’) even more burdensome than a notification that is substance related. What would be considered as the same article (eg same material, but different color; same color, same material, but different shape; etc)? A kind of ‘grouping’ of related ‘uses’ would need to be considered to reduce the administrative burden.

Q29: 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)

Q30: The following should be subject to notification requirements (tick all that apply):

Please explain:

The scope can only be defined by the concerns that would be addressed (if not yet covered by other legislation). Anyway, asking for information on all products (even articles with no intended release) can lead to an overarching vague of notifications that could hide any potential added value that could be brought by such a system. It was our understanding that concerns are mainly about 'new' nanomaterials (developed for special nanoproperties) and not on substances that 'became nano' due to the number based definition (eg pigments, fillers, ...). Whatever products could be subject to an obligatory notification, the provisions must be enforceable as well. Definition, measurement techniques, scope etc should be undoubtedly clear. Does it make sense to impose legislation for which compliance cannot be measured or controlled with an agreed standardised method by inspectors?

Q31: Is there a need to exempt certain types of nanomaterials?

Yes, certain types of nanomaterials should be exempted from a notification system

,

If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.)
Information that is already available for authorities, should not be asked again. Different legislative frameworks (REACH, CLP, sectoral frameworks such as biocides, cosmetics, food) already require health & environmental data and an assessment of the risks. However, this information should be clear for consumers and more easily accessible (eg via the web platform). Whatever products could be subject to an obligatory notification, the provisions must be enforceable as well. Definition, measurement techniques, scope etc should be undoubtedly clear.

Q32: Is there a need to exempt certain uses of nanomaterials?

Yes, certain uses of nanomaterials should be exempted from a notification system

,

If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.)
uses to be exempted: - Uses where the nanomaterial is embedded in a matrix and hence not available as such during the whole life cycle (including waste) - Uses regulated by sector specific legislation - Use of Non-intentional nanomaterials - Use of NM without exposure

Q33: 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

Q34: How should the information in a Nanomaterials Observatory be presented in order to reach the consumers, workers and authorities?

VBO/FEB believes that publishing (non-confidential) information on nanomaterials already regulated at EU level (ie used in food, cosmetics, biocidal products as well as substances submitted under REACH (once Annexes are adapted for nanomaterials) and CLP) would already increase transparency to a large extent and cover most needs.

PAGE 11: Section X - Potential use and benefits of a nanomaterial registry

Q35: In what ways could the information on nanomaterials from registries be potentially useful (tick all that apply):

- g) Other purposes (please specify)
All the potential benefits mentioned above can be obtained at lesser costs and easier way than to create a separate nano-inventory. Risk assessment and/or risk management is already done under REACH (and more clarifications are under development)

Q36: 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):

essenscia considers that the administrative burden, the risk of releasing confidential information and the negative expected impact on economy outweigh the potential positive impact of the scheme. Indeed, no benefit from the Belgian scheme is expected in the near future. Moreover, an EU inventory and a national inventory at the same time would be detrimental for the Belgian industry.

Q37: What would be the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration?

The only advantage might be that for industry one single EU register means less burdens than 29 different national registers in 29 different EU MS plus eventually the ones in EER but non EU Member States like Norway

Q38: Please provide any other comments that you would like to share regarding transparency measures for nanomaterials on the market.

On the basis of the experience gained by the chemical industry in France with the French notification scheme for nanomaterials, VBO/FEB would like to support the below comments from the French Chemical Industry Association, UIC, as we as well have identified the same concerns and difficulties during the discussions on the Belgian scheme.

First of all, UIC would like to raise the difficulties faced by companies in the context of the first year declaration exercise (2013).

Exercise (2015).

- The understanding/implementation of some definitions (“nanomaterial”, “intentionally manufactured”, “professional users”, “distributors”...), all the more that some of them have been adapted in a national context without consistency with the European ones (“importer”, “distributor”);
- The problem of nanomaterials characterization and the lack of validated methods, enhancing the uncertainties for stating if a substance is a nanomaterial or not;
- The difficulties when communicating in the supply chain (especially with suppliers outside France that were not aware of the regulation);
- The burden for companies, especially for SMEs;
- The broad scope of the scheme: why to report on substances marketed for decades without known health and environmental impacts? Why to report on non-hazardous substances?
- The issue of so precise and low quantities to be reported;
- The frequency of the reporting (once a year);
- The public report that can provide sensitive information (like the tonnage range when only one company declares).

But besides these difficulties, the main issues that UIC wants to underline are:

- The mistrustful perception of the scheme by economic partners and consequently, the negative impact on competitiveness and innovation: indeed, the French notification system has brought uncertainties amongst economic actors towards the French market, leading, in some cases, to question marks regarding business developments and location of R&D activities in France;
- The disruption of the free movements of goods within the EU as the French system is likely to create significant obstacles to trade of substances and mixtures;
- The questionable added-value of such a scheme (especially versus REACH and existing regulations) whose objectives can appear unclear.

In the end, UIC considers that the administrative burden, the risk of releasing confidential information and the negative impact on economy outweigh the potential positive impact of the scheme.

On the basis of the reactions collected from its Belgian member companies concerning the Draft Belgian Royal Nanomaterials Decree and the draft Belgian Nano-register, which has already been approved by the Council of Ministers and which has already been passed the Council of State, FEB/VBO would like to give the following comments on an eventual European Nano-register:

.1. A nano-register based on the “registration” above 100 g/year of nano-substances (that fall in the scope) and nanos in mixtures and their professional uses, and later on also the “notification” of nanos in articles and complex objects when there is a release above 0.1% of the nano added and their professional uses, is from many points of view too heavy and in some aspects unworkable for industry.

.2. The principle “No data no market” should be avoided in a legal text when it does not mean what it literally says. It creates confusion because in reality it means that data have to be given before placement on Belgian market, whereas no or insufficient data will only result in a fine, whilst access to market will not be blocked. In case “No data no market” really means “No market” it should not be mentioned either because in this case it blocks the free circulation of goods inside the Single European Market.

.3. The heavy administrative burden to collect all required data through a long, complex and multinational supply chain for the registration of substances (nano) & preparations (nano), and for the notification of articles (nano) & complex objects (nano) should be avoided.

.4. Does it make sense to impose legislation obligations for which there are not yet standards, testing methods, or affordable test equipment to measure certain legal requirements, and when there is no trained personnel with knowledge of nanomaterials and their testing methods in the long, complex and multinational supply chain? What do when inspection and industry have due to lack of standards both used in good faith different test methods?

.5. Some kind of confidential data (e.g. names of customers, uses and applications) asked for create problems for industry (what if a company does not want its use to become known to competitors?), and raises questions about possible data confidentiality problems (information leaks, computer viruses, etc.). It raises also the question of compensation to be given by the authority involved in case confidential information leaks out.

.6. In today’s existing and draft national nano-register legislation there are several missing or unclear definitions / wordings / phrases, and there is often little or no guidance in languages understandable by most suppliers in long, complex and multinational supply chains. This is very likely to result in wrong or no answers from EU and even more from non EU suppliers. This problem will increase with the number of different national nano legislations inside the EU.

Examples of unclear definitions from the Belgian nano Decree:

. If the European Commission changes its provisional “recommended” nano definition: ask again through the whole supply chain, and then declare / notify again? Can a registration / notification in a register be cancelled

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whole supply chain, and then declare / notify again? Can a registration / notification in a register be cancelled after a change in definition?

- . Placing on market? Only 1st time or every placing on market? What about “products in stock”, legacy parts?
- . Release? Over which time period? Waste/EOL, recycled included or not?
- . Pigment? Insoluble pigment? Which pigments are in / not in the scope?
- . What is a filler (nano)? What if nano is not used as a filler but for other reasons?

.7. The actual national nano legislation means very complex legislation especially for SMEs.

.8. How to find a solution for the missing communication about nanos and nano-legislation that creates at the same time more knowledge about nano legislation and more confidence in nanomaterials in the supply chain?

- . to professional downstream users in the supply chain?
- . to consumers in the market?

.9. Will the national registers have to be withdrawn or unified in case the EU should go for an EU nano register via an EU nano-directive? What about mutual recognition?