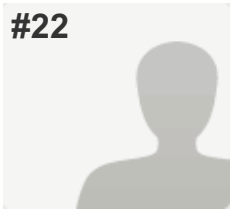

COMPLETE

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*:	European Precious Metals Federation
Town/City:	Brussels
Country*:	Belgium
Contact name:	Caroline Braibant
E-mail address:	
Transparency Register ID number (if applicable)	72702399216-46

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 , c) is a manufacturer of nanomaterials, d) is an importer of nanomaterials, f) is a manufacturer of articles containing nanomaterials without intended release , h) is a distributor of nanomaterials and/or mixtures 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

Primary business sector (NACE 4 digit code):	C24.4.1

Q7: Please indicate the number of employees.	1-9 employees

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).

Annual turnover	≤ €250k
Nano-related annual turnover	≤ €250k

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.

Nanomaterials	less than 6
Mixtures	less than 6
Articles	less than 6

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.

Nanomaterials	less than 6
Mixtures	less than 6
Articles	less than 6

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.

Nanomaterials	less than 6
Mixtures	less than 6
Articles	less than 6

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).

Number of customers	6 to 15
Number of suppliers	less than 6

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	4
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	5
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	Provide information yes, but in the right context to ensure proper interpretation and use, and avoid systematic stigmatisation

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	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)	3
d) Ensure consumer trust in products containing nanomaterials	1
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	3
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	4
g) Protect confidential business information	4
Please provide additonal comments	The learning curve of REACH and CLP implementation, in terms of Registration, Evaluation, and Authorisation processes, should not be underestimated. Launching additional measures should be truly complementary and not result in a duplication of work. Ideally, the EU should wait for 2020 (2018 + two years of 'buffer' time) to judge on what works more or less in the existing legislative framework, and then propose additional measures.

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	3
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way	2
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	4
Please provide additional comments	The various tools are aimed at collecting information, not at aggregating and reporting information for consumers. This is the real gap to be addressed: the proper aggregation and reporting of information to the public.

PAGE 5: Section IV – Health and environmental aspects

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 DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials , I am aware of significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials , Please explain your responses (if any, please report the nanomaterials, the health and/or environmental hazards, any relevant classification, any DNELs/PNECs/OELs, any exposure and in which condition): With the current definition of nanomaterial as recommended by the Commission, many workers are in theory exposed to nanomaterials. Whether this exposure is actually accompanied by a risk is to be determined in case-by-case risk assessments. In certain cases specific thresholds can be set for nanomaterials, but this again would be very dependent on the case itself. It is assumed that nanomaterials can display both an intrinsic effect due to their nature and composition, as well as a so-called 'particle effect' for which test methods are not really up to date yet.
Q17: **With regard to the past and current use of nanomaterials (tick the relevant box):**	I am aware of health and/or environmental incidents which have occurred , Please explain (if any, please report the events and any scientific publication): For example: single-walled carbon nanotubes may cause respiratory effects.
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: Unless the information that is collected via this registry is aggregated and communicated out in a contextual manner, it would just act as an information portal, maybe even possibly leading to 'disinformation', but would note enforce more safety on workplaces and consumer products.

PAGE 6: Section V – Consumer trust

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,

d) They would search for more information,

Please explain:
The effect of SVHC, SIN, and other similar black lists causes so much administrative, communication, and liability burdens that companies would possibly slowly move to using products which do not carry the prefix nano at all. However, because some of these materials are truly inert, and/or essential to the processes and sectors they supply to, industry would ensure their purchasing choice is a truly informed one, and not only one which follows speculative or collateral effects of sudden claims that products contain nanomaterials.

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:
Depends on whether the information just refers to the presence and not to the actual possible (non-) effect demonstrated by a given risk assessment for a particular use. The presence only would be related to a black-list effect, and would hence generate as a minimum, uncertainty as to the safety of the product the consumer is considering to obtain. Again, the public availability of information on the presence of nanomaterials should be accompanied with contextual risk information for it to do more than just informing consumers and to enable them to make informed decisions and choices.

PAGE 7: Section VI - Innovation and competitiveness

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:
If the EU registry adopts an approach similar to the approach followed by existing national registries then it appears that confidentiality is not breached. However, should the EU registry require more information and intend to make more information available to the public, confidentiality could be at stake. Though information on the identification, effects, and behaviour of a material cannot be claimed confidential, information on the uses of the material (which are addressed in the risk assessment) could, if published in excessive detail, result in the disclosure of CBI. Without knowing more about the intended EU registry, option c) above appears as a likely concern that industry would like to raise.

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)	e) hamper intra-EU competitiveness, f) hamper the competitiveness of European companies against extra-EU companies , Please explain As indicated in the response to the previous question, it all comes down to the level of detail that will be provided in the EU registry's dissemination portal. EU is part of a global economy where competition is hard and unfair in some sectors. Having a publicly available portal on uses of nanomaterials could actually facilitate the work of certain industrial spies who would have, through such a portal, an open book of areas to investigate on, and products to copy. As representative of an EU industry (with many legitimate activities in the US too), response f) above is likely to be more severe than response e) for the sector of precious metals.

PAGE 8: Section VII – Possible impact of a registry on your company/members of your association

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	4
c) with respect to articles with intended release of the nanomaterials	1
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)	3
Please explain:	Precious metals are used in nanoforms mainly as such and in articles without intended release, or better said, in articles where the nanomaterial is no longer a nanomaterial once it has been incorporated into the article's matrix. The EU registry could possibly result in a supplemental administrative layer of work.

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): As indicated in a previous question, without knowing more about the potential EU registry's dissemination portal, industry could precautionarily assume that some of the specific information and details requested in the registry could, unless they are aggregated or filtered, result in a disclosure of CBI. Furthermore, though identification, effects and behaviour information is not confidential, its generation may be costly and should not be made accessible to free riders (already the situation under REACH where some registrants just copy and paste information from ECHA's dissemination portal), or could reveal CBI if use-specific risk assessment details are divulged too.
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? Mainly related to: - Repetitive and iterative administrative work, including mistakes due to the varying nature of the existing schemes - Confusion, liability and legal claims due to language barrier and misunderstandings of requirements and spelling of responses provided
Q26: **Is the market for your nanomaterials/products containing nanomaterials significantly different from Member State to Member State?**	No, there is not any significant difference in the national markets for our products

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"?**

Possibly the scheme which foresees reporting obligations:
- where the nanomaterial is present in a consumer product (to avoid general stigmatisation around nanos which are only handled in industrial settings - or otherwise, foresee two different use sectors or registries)
- are implemented per use (to avoid general stigmatisation of nanos across uses and inform consumers on a use-basis)
- where information is put in context rather than published in raw form

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.

If the purpose is to allow consumers to make informed choices, as much contextual information as possible should be provided to them.
General notifications of substances would possibly trigger general stigmatisation if e.g. one use has been reported to pose risks for human health or the environment. Use-specific notifications would avoid this generalisation.
Furthermore, the notification per use also enables a notification of the form of the nanomaterial that is used for each use, thereby further preventing generalisation.
A notification per use also provides the necessary space to provide contextual information on the risk associated to that particular use.
From an administrative viewpoint however, notifications per use may be more burdensome to produce than others, and the frequency of the notification should perhaps be reduced to bi-annual or tri-annual notification obligations to compensate for this.
From a CBI viewpoint, ideally the notification per use should be done in agreed generic terms or product categories, to prevent the release of CBI.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):

e) Distributors to consumers (e.g. retailers),

Please explain:
The response to this question will depend on the purpose of the EU registry: - If the purpose is to inform consumers, there would be no added-value for actors away from consumers to perform this notification, and in the best case it would be for c), d), and e) to notify. - If there is an objective of traceability or leverage on upstream actors to provide information (because the presence of nanomaterials may not be communicated systematically from upstream to downstream), then actors a) and b) should be required to notify too. However, it should be noted that in some/many cases, even when a nanomaterial is used for the manufacturing stage, it may no longer be present in the material supplied by a) and b) to actors c), d) and e).

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

c) Articles with intended release of nanomaterials

,

Please explain:
The response to the above question will depend on the category under which consumer products would fall, and whether the product use can itself result in a potential exposure to the nanomaterial as such during its use life, which would pose a risk. Category c) clearly has this exposure potential (which does not necessarily mean that there is a risk for the user); but in general all categories a) to d) could during use result in an exposure of the user to the nanomaterial itself, assuming that the nanomaterial is present in the product in a form that can be released. Rather than focussing on categories a) to d), notification should apply for any use of a product containing a nanomaterial in a form that can be released during its use life, and pose a risk for the environment or human health upon release.

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.) If notification would apply for any use of a product containing a nanomaterial in a form that can be released during its use life, and pose a risk for the environment or human health upon release, any product that would not fulfill the above criteria should not be subject to (mandatory) reporting. For those products which do not fulfill this criteria, the consumer could be redirected to the REACH risk assessment disseminated on ECHA's portal, for efficiency.
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.) As said above, uses for which the absence of risk could be demonstrated should not be subject to a mandatory reporting in the EU registry, as long as evidence of this absence of risk is available from another credible source, such as the ECHA dissemination portal. This is case-specific cannot be prejudged upon for the purpose of the response.

PAGE 10: Section IX – Nanomaterials Observatory

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 , f) Other (please explain): All credible sources of information should be considered. The credibility will among other things be verified by applying the relevant validation and interpretation criteria, by a panel of experts including academia, Member State experts,industry experts, and NGO experts to achieve a balanced and credible outcome.

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

- Short and simple wording
- No emotional adjectives
- Links to relevant risk assessment guidance and
- Name and background/affiliation of experts who took part in the assessment
- Contact of the industry association representing the sector manufacturing the nanomaterial and use that is notified
- Option to react to incomplete/incorrect dataset via template (similar to Wikipedia)

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):

a) Risk assessment and/or risk management,

c) Promotion of safe use of nanomaterials in products

,

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

,

e) Informed purchasing decisions by consumers

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):

Communication up and down the supply chain is sometimes interrupted; the EU registry could be used by REACH registrants to collect practical information on the use of the (precursor to the) nanomaterials they supply.
Having a well equipped tool would not only inspire producers to act diligently but could discourage illegitimate market actors to penetrate the market.
A registry which focusses on uses of nanomaterials for which there is a unconfirmed or confirmed risk could allow defining targeted regulatory policies and academic research, informing the various funds of the areas which truly require the generation of infor-mation.
Ultimately, a EU hosted tool would probably be 'trusted' by consumers who would select this tool instead of or in complement with other tools to make a truly informed choice.

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

If its purpose remains one of supporting consumers in making informed decisions, it would not duplicate the existing tools in place like REACH.
If it is established per use in consumer products (with a lower frequency than the proposed annual one), it would really respond to consumer questions rather than submerge them in excessive and useless out of context information.
If it is build on the basis of categories of uses or product codes (together with the lower frequency), it would decrease the administrative burden on notifiers and their concern that unnecessary release of technical performance details and other CBI could occur.

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

To ensure full transparency of all available information supplied as part of regulatory schemes, besides a focussed use of the EU registry for uses in consumer products where the user could be potentially exposed to the nanomaterial as such, the REACH datasets of nanomaterials should ideally be translated into shorter versions accessible to the public, by credible panelists.
Similar to SCENHIR opinions, it would be useful to have short reviews published by similar agencies, on the effects confirmed of each substance in nano form after is has been validated as part of a formal process such as REACH Evaluation or Authorisation.