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COMPLETE

Collector: Nano Consult - Industry (Web Link)
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PAGE 2: Section I - Identification

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

Organisation*:	Union des Industries Chimiques (UIC)
Town/City:	Puteaux
Country*:	FRANCE
Contact name:	Philippe Prudhon
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Transparency Register ID number (if applicable)	0935153658-47

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,
- e) is a formulator of mixtures containing 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

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

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 | 1 |
| 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 | 1 |
| 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 safe use of the products that are placed on the market. By this way, with relevant explanation on the process provided to the public, consumer trust could be increased. 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)

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	4
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	Do not know
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.	Do not know
g) Protect confidential business information	3
Please provide additional comments	<p>UIC believes that, as for any other chemical, 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. In some cases (cosmetics, biocides,...), labelling requirements exist as they were found relevant by the legislator for information purposes. The added value of such labelling requirements is not demonstrated yet. 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.</p>

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 | 3 |
| e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market | 5 |

Please provide additional comments

The adequate response to health and environment risks is not linked to the information on the presence of NMs in products but to an effective and reliable risk assessment carried out for the whole life-cycle of the substance (as foreseen by REACH and product-specific regulations). For the time being, labelling requirements for information purposes have not been perceived as effective. The added value of such requirements remains even questionable. As regards question e), on the basis of the experience gained by the chemical industry in France with the French notification scheme, UIC confirms that such a national system can create obstacles to trade within the internal market.

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

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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):
NIOSH set up indicative exposure limit values for TiO₂ and carbon nanotubes.

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

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If appropriate, please explain further:
UIC believes that risks can be controlled by the implementation of the current European regulatory framework (REACH, CLP 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 Safety Data Sheets as regards industrial and professional users. Hence, the added value of an EU registry as regards risks decrease is questionable.

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,
- c) Their purchasing decisions would not be affected

Please explain:

The implementation of the French notification scheme for NMs showed that situations b) and c) occurred within the supply chain. As regards situation b), customers 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.

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

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:

UIC would like to contribute on the basis of the experience gained by the chemical industry in France with the French notification scheme for nanomaterials. Indeed, the implementation of this national registry system led to a mistrustful perception from our economic partners and consequently, to a negative impact on competitiveness and innovation. More precisely, it brought many uncertainties amongst economic actors towards the French market, creating, in some cases, question marks regarding business developments and location of R&D activities in France.

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

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 | 5 |
| 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) | 1 |

Please explain:

As chemical industry, an EU notification would mainly impact substances and mixtures.

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.

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 notification obligations increase the workload for companies.

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

Respondent skipped this question

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"?

- Transmission of the notification numbers along the supply chain in order to minimize the burden for companies and protect confidential information
- Consider as much as possible information as CBI in order not to hamper more competitiveness and innovation

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.

The type of notification (per use or per substance) is directly linked to the goals of the notification schemes. For consumers, notification per use should be more relevant, whereas for authorities and downstream users, notification per substance could be more useful.

Anyway, as UIC considers that REACH and CLP can be a good start for a “NM observatory” without any further scheme, a “substance-based system” seems more appropriate.

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

Please explain:

Actors can only be defined when the goals of the scheme are clearly established. Indeed, the actors impacted along the supply chain will depend on the objectives foreseen (traceability for workers? Consumer information?...)

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

Please explain:

See above question n°2. The scope of the scheme can only be defined when its goals are clearly established. Anyway, asking for information on all articles (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.

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

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

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If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.)

- NM registered under REACH or covered by a sectoral legislation with NM specific requirements (Biocides, Cosmetics,...)

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

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

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If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.)

- At least, uses covered by sectoral legislation (Biocides, Cosmetics,...) - Uses leading to no exposure to human health and the environment should be exempted as well. This covers nanomaterials embedded in matrices and not available as such during the whole life cycle.

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,
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?

The REACH dissemination database and the work engaged by ECHA on Brief Profiles could be a good start.

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):

Respondent skipped this question

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):

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. Indeed, no benefit from the French scheme has been identified so far, at least from a consumer perspective.

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

No added value identified so far.

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, UIC would like to contribute to the ongoing public consultation on the Impact Assessment on Possible Measures to Increase Transparency on Nanomaterials on the Market.

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

- 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.

